

Final Study Report
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A Study of the Feasibility and
Advisability of State Vaccine Purchasing
Options

Submitted to:
The Statewide Advisory Commission on Immunizations



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Executive Summary

A research team brought together by the Schaefer Center for Public Policy at the University of Baltimore was tasked with studying "[a]ll available options for the purchasing of vaccines, including the development of a universal vaccine purchasing system, or a similar program to increase access to necessary vaccines, for the State."

The team began by studying the existing stresses on the system and found that there are important challenges confronting children and adult vaccine policy in Maryland. The primary challenge facing the children's vaccine policy is the increasing administrative and financial burden being placed on providers.

There are several challenges facing adult vaccine policy, including:

- Low flu immunization rates in the state (latest data—Maryland ranks 36th out of 50 states)
- Past shortages of vaccine
- Inequitable distribution, both by timing and by quantity
- Rapidly changing supply and demand

The study found that Maryland's Immunization Reporting System needs strengthening to respond to future needs. In the past, Maryland has done a good job of providing immunizations to the uninsured and the underinsured, and it must continue to do so. However, there are also several challenges related to purchasing policies that create a context that restricts feasible policy options. First, the federal Employee Retirement Income Security Act of 1974 (ERISA) restricts the applicability of state mandates requiring certain actions by many of the self-insured employers' that operate in the state. Second, national policy changes that would change the policy environment are being debated and are not resolved. Third, policy options must be able to respond to the need for crisis planning.

The research team investigated what other states are doing and found that:

- Universal Vaccine Purchase Systems are perceived to be very expensive.
- Future increases in cost and the number of recommended vaccines should be anticipated.
- Decreased Section 317 grants and other public funding sources shifts the cost of a Universal Vaccine Purchasing System over time to other funding sources such as the State.
- Using private funds might necessitate purchasing non-Vaccine for Children (VFC) vaccines, further increasing costs.
- A strong immunization information system and a strong ordering and distribution system should be in place if a universal purchase system is to work effectively.
- If a Universal Vaccine Purchasing System is adopted it should include funding mechanisms that allow the state to include new vaccines quickly, but the transition should be carefully planned.

The research team conducted multivariate analyses and found that:

- There is no statistically significant difference in immunization rates between Universal Vaccine Purchasing System states and VFC enhanced states like Maryland.

- On many dimensions VFC enhanced states outperform Universal Vaccine Purchasing System states. For example, on the CDC's 4;3;1;3;3;1 measure 77.18 percent of children in VFC enhanced states met the standard compared to 74.5 percent of children in Universal Vaccine Purchasing System states.
- Controlling for variables that the literature suggests may influence immunization rates, such as the percentage of children in the state living in poverty, the percentage of children in the state who are uninsured, and the population per square mile of the state made no difference in the basic analytic results. Controlling for these variables, the analysis of states with VFC enhanced programs, like Maryland, had immunization rates on each the basic vaccines and on the combinations of those vaccines that were not significantly different, statistically, from the rates of those states that have continually bought and provided those vaccines to their residents without charge.

The research team conducted a survey of 422 vaccine providers in Maryland and found that most providers were very supportive of a universal vaccine purchase system, though a minority was strongly opposed. When respondents were told that "There is a proposal that the state of Maryland buy and distribute all the required children's vaccines, not just the vaccine for VFC children," and then asked "On a scale of 1 to 10 with one being not at all supportive and ten being very supportive, how supportive would you be of Maryland establishing such a program?" 71.3 percent answered "10, very supportive" and 5.8 percent answered "1, not supportive at all."

The survey also showed that about one half of respondents reported that storing and providing vaccines has become a significant financial burden for them.

Given these findings, the research team does not recommend any direct changes in the state's actual purchasing of vaccines at this time. The team cannot recommend universal purchase because of its high cost and its lack of proven efficacy in increasing immunization rates or alleviating the main stresses faced by the immunization provision system.

The team does, however, recommend changes related to vaccine purchasing in order to ameliorate some of the stresses facing the system and prepare for additional changes in purchasing policy, should they later prove necessary.

Among other things the research team recommends:

- An increase in Medicaid administration fees for immunizations.
- That the state provide some incentive to providers for participating in an Immunization Information System.
- That the state mandate that Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention recommended vaccines not be subject to co-payments.
- That the state create a public reporting system and require health plans to report their reimbursements to cover the costs of vaccines and vaccine administration.

To take a stronger, pro-active position, the state of Maryland will need reliable, dedicated funds to do so. One way to generate needed funds is to establish an assessment system that would assess an annual fee on "insured lives," as other states have done. .

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Section 1 - Introduction

Senate Bill 105 was enacted into law, expanding the duties of the Statewide Advisory Commission on Immunization. The law requires the Commission to study and make recommendations about, among other things, "All available options for the purchasing of vaccines, including the development of a universal vaccine purchasing system, or a similar program to increase access to necessary vaccines, for the state." The Schaefer Center for Public Policy at the University of Baltimore assembled a team of researchers from the University of Baltimore and other institutions to conduct a study that would gather information for the Commission and provide recommendations for the Commission to consider. This report presents this team's findings and recommendations. It should be emphasized that all opinions and recommendations in this report are the opinions and recommendations of the research team and not those of the Commission.

The research team examined both vaccines for children and other vaccines for the general population. The first step in the project involved creating a list of options for vaccine coverage, purchasing, financing and distribution based on what other states have done and by asking experienced observers for their recommendations. Findings from this analysis of possible options were delivered to the commission on July 17, 2007.

After consulting with the Commission, it was decided that, when evaluating an alternative, the research team would ascertain whether the alternative furthers: 1) the building and maintenance of a sustainable vaccine delivery system that will at least maintain and, where possible, improve immunization rates in the State, not just in the immediate future but for years to come; and 2) an improvement the system's ability to continue to function in crisis environments.

A Preliminary Report with preliminary recommendations was provided to the Commission on October 1, 2007. On October 18, 2007 a presentation was made to the Commission, describing a series of more specific recommendations. This Final Report includes nearly all the content of the Preliminary Report, as well as more specific recommendations and facts not presented earlier. This document also responds to issues raised in the discussions with Commission members at the meetings held on October 18, 2007 and November 13, 2007.

Before Senate Bill 105 was enacted in the Spring of 2007, the Center's preliminary estimate was that an exhaustive study of the advisability of instituting a universal purchase system for children's vaccines alone would require over a year to complete. But after the legislation was enacted it became clear that the study both would be of broader scope and would have to be done in much less time. The essentials of this study, which includes not only universal purchase for children's vaccines but "all available options" for vaccine purchase systems, had to be completed within four months. In early discussions with state officials, research team members expressed concern about this limitation and state officials said that they realized that the research team could not study all available options in depth.

As a result, the team did give its considered recommendations about "all available options" that were found proposed in the literature or by stakeholders. However, explanations of the technical details and assumptions that were used in the various analyses were abbreviated because of the short time frame. It must also be acknowledged that additional time and further study might have yielded different recommendations about some of the options. In general, though a study given more time would likely have produced more precise cost estimates and more evidence, the team believes the most important recommendations for action would have been the same as this report, which had to be completed in a shortened time frame.

To keep the study as relevant as possible for the Advisory Commission, given this time limitation, at many points the research team asked the Commission for specific feedback and any guidance they could give as the work progressed and they were apprised of the status of the results. When the Commission as a group, or when specific Commissioners, provided suggestions those suggestions were noted, followed up, and addressed.

The first step in communicating with the commissioners was taken on July 17, 2007. At the Commission meeting of that date the research team made a presentation, summarizing its perceptions of the primary issues involved. This presentation and the subsequent discussion became the foundation of a short summary of the goals and direction of the research which was forwarded to the Center's project manager to give to the commissioners on August 2. In the email accompanying that summary, the research team asked the project manager to convey to the commissioners that suggestions about further clarifications would be welcomed. That email also welcomed the commissioners' suggestions about which stakeholders might be interviewed or the questions for which they sought answers from the stakeholders. Two commissioners responded to the invitation to provide further clarification about the goals and directions, and the team worked to address the points that were raised.

One shortcoming of this study that resulted from the short time frame is the relative lack of stakeholder interviews from the insurance industry. The team's inability to engage representatives of that industry led the team to ask the commission for specific help in this area. In an email to the project manager of August 27, 2007, the Center's project manager asked for such help. In response, Dr. Charles Medani, CareFirst BlueCross BlueShield Medical Director and a member of the Commission volunteered to be interviewed. The interview with Dr. Medani was very informative on many issues but did not lead to other contacts in the insurance industry. The research team contacted two different officials with America's Health Insurance Plans (AHIP), a group that represents the insurance industry, including Bob Rehm who had worked on AHIP's Immunization Assessment Summary in November 2005 and who is now Director of Public Health Strategies for AHIP. Neither of these representatives accepted our invitation to be interviewed. Unfortunately, these results and the time constraints left the research team with only the one interview and the literature review as resources for trying to understand the insurance industry's perspective on the issues involved.

Another meeting was held with the Commission on October 18th, at which the preliminary research results were presented. In the discussion that followed some specific suggestions were made that were incorporated into the preliminary final report. The Commission met again on

November 13th to discuss the preliminary final report and ask questions of the research team. The questions led to suggestions for changes and those changes that could be accomplished in the two weeks before the final report was required were included in the final report of November 30, 2007.

Section 2 of the report summarizes the methods used in the study. The methods section is followed by Section 3 which includes the general findings of the study. Section 4 presents findings specific for Maryland. The final section, Section 5, includes a discussion of the recommendations concerning each option for revision of the vaccine purchasing and delivery system that was suggested in the literature or in stakeholder interviews.

Section 2 - The Methods Used in the Study

This report is based on a systematic literature review, interviews with state officials and other stakeholders and experts, analysis of the National Immunization Survey, and a telephone survey of the medical office practices of Maryland physicians who administer vaccines.

Method 1 - Stakeholders and Expert Interviews

To expedite the interview process, interviews were conducted with an intentional "snowball" sample of national, state and local officials, representatives of provider organizations, representatives of other professional organizations, providers, state administrators associated with vaccine programs, representatives of vaccine distributors, and vaccine manufacturers. We asked many of these interviewees to identify groups or individuals who might have informed opinions on or a stake in the issues, and we used that information to build our stakeholder list. A list of many of the completed interviews is provided in Appendix A.

Method 2 - A Systematic Literature Review

Searches were conducted in academic database sources such as Lexis-Nexis Academic and Academic Search Premier, the National Library of Medicine's *www.pubmed.gov* site as well as general internet searches to identify literature on topics relevant to this study. For a partial list of these sources see the bibliography attached to this report in Appendix F.

Method 3 - Multivariate Regression Analysis Using the National Immunization Survey (NIS) Data and Other Sources

Multivariate regression analysis using the National Immunization Survey (NIS) data and other sources was conducted to ascertain the nature and extent of the relationship between universal purchasing systems and immunization rates. Data analysis using population density as a surrogate for other demographic variables found that universal purchase does not appear to be associated with improvement in immunization rates as measured by the NIS. In fact, on many vaccine coverage measures, "VFC enhanced" states like Maryland outperformed the universal purchase states.

The literature review suggested that population density, the percentage of children in the state living in poverty, the percentage of children in the state who are uninsured could be variables related to the success of a state in providing immunizations to its children. Each of these variables was included in the analysis. The analysis used multiple measures of success in immunizing children. Data from the National Immunization Survey for the most recent available past 5 years (2002 through 2006) were used.

These analyses are limited by the fact that only 15 states had universal purchase systems that covered the vaccines needed for the immunizations on which measures of success were based. A further limitation is that only 10 states, including Maryland, had vaccine provision systems classified by the CDC as "VFC enhanced" states. These 10 were the states whose systems were

compared to the universal purchase states to see if there was statistical evidence that such states had superior systems of vaccine provision.

The analysis was also limited by the nature of regression analysis. It may have been that another explanatory variable added to the analysis could change the results.

Method 4 - Interviews of Officials in Key States

Key actors were interviewed in universal purchase states and those states that have recently changed status or considered changing status. These interviews were conducted from August 1, 2007 through October 31, 2007.

To supplement our literature review, in those states which where stakeholders were not interviewed, we attempted to contact the immunization directors. In each of these states where we could talk directly or leave messages we asked if there state had conducted a study related to universal purchase. No director whose state we had not found through our literature review responded that their state had conducted such a study.

Method 5 -Telephone Survey of Immunization Providers in Maryland

After the first stages of the literature review and the stakeholder interviews, a survey instrument was designed. As required by the contract, the goal was to survey at least 400 offices of immunization providers in the state of Maryland. When the survey period closed on October 18, 422 Maryland Vaccine for Children (VFC) and non-VFC pediatric and family practice vaccine providers completed the survey. The survey was designed to assess respondents' experiences and opinions about a variety of issues. When the complete list of VFC providers and other pediatricians had been exhausted, the survey was adapted, with only slight changes in language, for providers in family practice environments.

Respondents were asked about logistics such as supply problems, costs, waste due to expired vaccine, difficulties of managing both publicly supplied and privately supplied vaccines, and missed opportunities for immunizations that might be caused by temporary supply shortages. The role of professional fees for vaccinations that encourage or discourage private office vaccinations was also explored as part of the survey.

It may appear that some of the survey questions are "leading" questions. Many of the questions that appear so are "contingent" questions that were asked only of provider practices that had already indicated a problem. Other questions are "closed-ended" that offer specific alternatives when, had there been more time to analyze the results, the team may have preferred to ask an "open-ended" question. The team kept in mind that this survey was needed, in large part, to ascertain the extent to which the assertions made in the literature about difficulties faced by practices were congruent with the perceptions of practitioners in Maryland. Thus, when the questions needed to be closed-ended the research team endeavored to provide alternatives suggested by the literature.

A copy of the survey with the final results for each question can be found in Appendix B.

Sample Design

We obtained a preliminary list of providers from the Vaccine for Children (VFC) program administrators in Maryland. This list was supplemented by a search of public sources of other venues where vaccines may be given but are not affiliated with the VFC program. The list of other pediatricians was generated by taking the publicly provided internet list from the Medical and Chirurgical Society of Maryland's (MedChi) list of pediatric specialists and screening by phone number and address to remove those entries already on the VFC provided list. A study of immunization rates in five selected counties, conducted by the Schaefer Center in 2005, found that about 94 percent of facilities that provided immunizations in those counties were affiliated with the VFC program.

Our research team merged the lists to remove providers or provider offices which had the same doctor's name, mailing address, or telephone number. This was done in order to minimize the incidence of duplicate survey responses from a single practice or provider's office. An additional safeguard to minimize the incidence of duplicate survey responses was to ask the respondents if they had answered this survey in the past month. If a respondent answered that someone in the office had, the survey was terminated.

Who was interviewed?

Medical practices that might provide immunizations were identified in three ways. First, a list of all VFC providers was obtained. Most of the respondents (353 of 422) were identified through that list. Second, the public, internet-based list of MedChi members was used to identify telephone numbers of additional practices listed as pediatric specialists. Twenty-two additional practices were contacted through that the MedChi list (though 12 of those were also VFC participants). Thirdly, the list of MedChi members was used to generate an additional 47 practices that were identified as family practice specialists.

Our survey targeted the "person in your office who orders and tracks your vaccine supply." The respondents who were ultimately self-selected as the persons most knowledgeable about these areas included physicians who managed multiple physician practices, physicians who were sole practitioners and nurses and/or office managers whose duties included tracking and ordering vaccine supplies.

When possible, surveys were completed by a single person, however since some of the questions crossed from one person's area of practical knowledge into another's, additional people were sometimes interviewed. For example, an office manager might be very knowledgeable about tracking and ordering vaccine supplies, but might not be knowledgeable about the business/cost benefit decisions which lead to the office deciding to supply one vaccine, or combination of vaccines, over another. In cases where multiple persons were required in order to complete the survey, respondents were encouraged to transfer the interviewer to the appropriate person or to conference the appropriate person into the interviewer's call.

Survey Implementation

Telephone interviews were conducted between August 29, 2007 and October 18, 2007, between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday. The survey was administered via the Schaefer Center's Computer Aided Telephone Interviewing (CATI) lab by professional telephone interviewers. A non-random sample was selected using lists of providers, who were expected to be in a position to provide assessments and experiences with the current VFC program, vaccinating non-VFC children, and additional experiences that led past VFC providers to abandon the VFC program.

The Schaefer Center Survey Lab features a full capacity CATI system, which allows for sophisticated questionnaire branching, in order to tailor specific questions to specific types of respondents. Because of this, both VFC and non-VFC providers were able to complete the same survey, although their answers to screening questions would allow only VFC providers to answer questions about the VFC program.

Completion Rates

From the total sample of 992 phone numbers, telephone interviewers made 3,804 phone call attempts. An average of 3.83 attempts were made to each number, with a total of 422 completed surveys. The completion rate for the survey is 42.5%

Section 3: Findings

1. There Are Important Challenges Confronting Vaccine Policy in Maryland

Vaccines are one of the most cost-effective public health measures. In 2001, the Centers for Disease Control and Prevention (CDC) evaluated the combined impact of routinely giving children DTP, polio, Hib, MMR, Hep B, and varicella vaccines as part of the recommended childhood immunization schedule.¹ The CDC estimated that these vaccines will prevent more than 14 million cases of disease and more than 33,500 deaths during the lifespan of children born in 2001. Administering these vaccines prevents not only disease, but also saves time spent seeking care or caring for ill children, resulting in a net saving in excess of \$40 billion in the US each year.

A highly vaccinated population is important for two reasons. Individuals who are fully vaccinated are protected from developing the vaccine-preventable disease. In addition, they cannot pass the disease-causing bacteria or virus to others who are not fully immunized; thus, the disease cannot spread in the community. There are several reasons why individuals are not fully immunized. They may be too young to be vaccinated, have a medical contraindication to the vaccine, or cannot mount an adequate immune response to the vaccine. Others have simply not received the recommended doses, primarily because of provider or personal/parental factors.

We find that there are complex challenges facing the continued efficacy of vaccine policy in Maryland. The challenges facing vaccine policy for children are quite different than the ones facing adult vaccine policy. We describe the challenges facing vaccine policy for children first.

2. Challenges Facing Children's Vaccine Policy—The Increasing Burdens on the Providers

We found that, although current immunization rates in Maryland are generally well above the national average, recent changes in the number and price of vaccines, together with reimbursement rates that have not kept up with the actual costs of vaccines and vaccine administration have a significant probability of damaging the existing system of vaccine provision. We start by examining the current situation.

2.1 Vaccine Coverage Rates for Children in Maryland

Each year the CDC conducts the National Immunization Survey (NIS) to obtain national, state, and urban vaccination coverage rates for children. In 2005 and 2006, almost 80 percent of 19-35 month-old children in Maryland and nation-wide had received all vaccine doses recommended for their age. Coverage rates for each recommended vaccine were higher; for example 96 percent of surveyed children in Maryland had received the recommended three doses of Hib vaccine.² Table 1, summarizes the percentage of US and Maryland children between 19 and 35 months of age who were up-to-date for the recommended vaccine series and individual vaccines in 2005 and 2006, as reported by the US Centers for Disease Control, National Immunization Survey.

Table 1

Percentage of US and Maryland Children, 19-35 Months of Age, UTD for the Recommended Vaccine Series and Individual Vaccines in 2005 and 2006 (NIS Data)								
	US	Maryland						
	4:3:1:3:3:1 *	4:3:1:3:3:1 *	4 DTP	3 Polio	1 MMR	3 Hib	3 Hep B	1 Varicella
2005	76.1	78.6	90	92	94	96	93	91
2006	77.0	78.3	87	93	96	96	92	94
<p>*4 DTP, 3 polio, 1 MMR, 3 Hib, 3 HepB, and 1 varicella</p> <p>DTP = Diphtheria, Tetanus, Pertusis; MMR = Measles, Mumps, Rubella; Hib = <i>Haemophilus influenzae</i> type B; HepB = Hepatitis B</p> <p>http://www.cdc.gov/vaccines/stats-surv/imz-coverage.htm#nis</p>								

High rates of vaccine coverage will only be maintained in Maryland if: 1) population coverage rates are routinely monitored; 2) there is an adequate supply of vaccine; 3) health care providers can easily access a child's vaccination history and take every opportunity to vaccinate (avoiding missed opportunities); 4) parents continue to recognize the importance of vaccines, have access to vaccine providers and seek timely vaccinations for their children; and 5) parents and providers are not thwarted by financial constraints.

While Maryland's current children's vaccination rates are relatively high, some parts of the current delivery system are under stress. Health care providers have expressed growing concern that financial barriers may lead to a decline in vaccination coverage in the future as additional and more costly vaccines are developed and are included in the list of nationally recommended vaccines. The American Academy of Pediatrics' (AAP) recent report, *Immunization Financing: Where is the Breaking Point*, articulates some of the challenges that Maryland faces, including

- An increasing number of new and expensive vaccines.
- Inadequate reimbursement to cover vaccine-related cost.
- Significant lag times between introduction of a new vaccine and health insurance coverage of the immunization.

Table 2

Cost of VFC and Privately Procured ACIP Recommended Vaccines per Child 0–18 Years

Vaccine	#	VFC \$	Private \$
Hepatitis B (Hep B)	3	27.30	64.11
Diphtheria, Tetanus, Pertusis (DTP)	5+1	94.00	141.05
<i>Haemophilus influenzae</i> type B (Hib)	4	43.32	91.08
Polio	4	44.24	91.20
Measles, Mumps, Rubella (MMR)	2	35.20	89.68
Varicella	2	118.30	149.12
Rotavirus	3	165.15	200.82
Pneumococcal	4	248.56	294.80
Hepatitis A (Hep A)	2	24.50	57.48
Influenza	4	40.61	46.88
Meningococcal	1	73.09	89.43
Total	35	914.27	1316.00
Human Papillomavirus (HPV)	3	290.25	361.50
Costs are for vaccines only. Cost varies somewhat by manufacturer and if combined with other antigens. From http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm (7/2007 price list)			

Several factors contribute to jeopardizing the current system:

2. 2 Increasing numbers of new and expensive vaccines

While vaccine prices vary by quantity ordered and procurement source (privately from the manufacturer or from the CDC using VFC or other governmental funds), the cost for “older” vaccines (DTP, polio, MMR, Hib, and Hep B) is relatively low. The price of newer vaccines such as varicella, rotavirus, pneumococcal, and HPV, however, is much higher now and may remain high because FDA laws prevent the manufacture of generic vaccines. According to the AAP, in 1980, vaccination costs in a private office for the seven injections recommended for children at that time totaled \$22.65. In 2006, 22-33 injections are recommended, with a total cost of \$1,641.13. The costs in 2007 are estimated to be slightly higher (Table 2) and more new vaccines are likely to be recommended in the future.

As of 2005-2006, the cost of vaccines recommended in early childhood does not seem to have prevented Maryland children from being fully vaccinated. Children who receive Medicaid or who are underinsured are eligible for free vaccines through the Vaccines for Children (VFC) program. Health care providers, however, have expressed growing concern that financial

barriers may lead to a decline in vaccination coverage in the future as additional and more costly vaccines are developed and are included in the list of nationally recommended vaccines.

2.3 Cost of Vaccine Purchase, Handling and Administration

Vaccination costs include the purchase price of the vaccine, as well as overhead and vaccine administration costs incurred by the provider. Maryland's Vaccines for Children (VFC) program purchases and distributes vaccines to providers for children who receive Medicaid or who are underinsured. Providers must purchase vaccines from manufacturers or wholesalers for privately insured children.

Vaccine administration costs include determining, at each visit, if the child is due a vaccine and the time required to counsel the parent regarding the efficacy and safety of each antigen and to obtain permission to vaccinate, as well as supplies such as gloves and needles. Staff time is needed to chart the vaccine, update the state's vaccine registry, and bill the child's insurer. Separate records must be maintained for VFC and non-VFC vaccine. In addition, providers may elect to send visit and vaccination reminders to parents of children who are due or past-due for a vaccination.

Overhead costs include ordering and tracking vaccines and purchasing and maintaining refrigerators to store vaccines, as well as insurance on the inventory. Because improperly stored vaccines degrade, providers must routinely monitor the refrigerator temperature and discard vaccines that may have expired or have been rendered inactive due to power or appliance failure.

Thus, to be financially solvent, a provider must, in a timely fashion, be able to recover the cost of purchasing and storing a vaccine, as well as the labor costs of identifying children who are due a vaccination, counseling parents, completing requisite paper work, inventorying and ordering new vaccine, and physically administering the vaccine. While the VFC and most private health insurance plans cover some of the costs for immunizations, they do not cover the entire cost.

2.4 Inadequate reimbursement to cover vaccine-related cost

Most private health insurers cover immunizations. Both private and public insurance plans reimburse separately for vaccine purchase and vaccine administration costs, however vaccine-related overhead costs are not specifically included in either reimbursement. For example, the cost of recording vaccinations in state registries may not be covered by insurers. Several other changes in repayment practices have contributed to inadequate reimbursement:

- **Vaccine Purchase:** According to the AAP, "In the past, health insurance plans have reimbursed vaccine acquisition costs based on the average wholesale price (AWP), which is usually determined by the list price of the vaccine plus 20 to 25 percent to cover other costs incurred by vaccine providers. More recently, insurers have turned to the lower average sales price (ASP) to benchmark payments." That is, reimbursement for

purchasing vaccines no longer includes an added 20 to 25 percent for other vaccine-related costs.

- **Vaccine Administration:** Most private insurance plans reimburse for vaccine administration costs at rates that are similar to those paid by for VFC children by the state's Medicaid. The maximum allowable Medicaid payment for vaccine administration is \$18.00; however, Maryland's Medicaid vaccine administration reimbursement is only \$10.00 per "shot." Physicians, therefore, may be reluctant to administer combination vaccines because of the "per shot" policy. Combination vaccines reduce the number of "sticks" for the child and are associated with better on-time vaccination rates. There is, however, no reduction in the time physicians must spend counseling parents, obtaining consent, and charting for each antigen.
- **Vaccine-related Overhead:** The AAP estimates that vaccine-related overhead adds 18 to 25 percent to the cost of the vaccination, however as noted earlier, most of these costs are not currently reimbursed by public or private payers.

Lag time between the recommendation for a new vaccine and insurance coverage

According to the AAP, private health insurers often do not reimburse physicians for the purchase, administration, and overhead costs of new vaccines until the provider can renegotiate his/her contract with the plan.³ Insurance plans, however, state that the provider is responsible for providing all recommended vaccines.

2.5 Financial stresses on providers

The AAP reports that the doubling of the number of recommended vaccines in the last 15 years and tight financing are creating a condition where providers question their ability to continue offering these services. Their 2007 report, *Immunization Financing: Where is the Breaking Point*, states that "Although primary care providers have universally embraced immunization as a core competency, recently the pressures of a rapidly increasing number of vaccines and tight financing are making primary care providers question their ability to continue to offer immunization services. The number of vaccines recommended for routine use in children has doubled over the last 15 years. The demands on primary care practices to deliver the current standards of immunization practice have increased substantially as a result." As an example, the San Francisco Chronicle recently reported that "Some pediatricians, faced with a growing number of recommended immunizations and rising prices, are starting to restrict or refuse to administer some vaccines unless patients pay in advance—and the prices can add up to hundreds of dollars."⁴

This anecdotal evidence, while not a basis for making conclusions about the scope of the problem, does describe a context within which some see the problem. The New York Times reported many similar anecdotes in an article entitled "Pediatricians Voice Anger over Costs of Vaccines" (March 24, 2007). One of those stories is of a pediatrician in Tennessee. "Teri Perryman, a doctor in Kerrville, Tex., is not only avoiding Gardasil and RotaTeq, but also not

offering the new meningitis vaccine, flu shots or new expensive combination products like one that combines the chickenpox vaccine with the measles-mumps-rubella vaccine, according to her husband, Kevin Perryman, who helps manage the practice.”⁵

Our survey responses, literature review and stakeholder interviews convince us that there is a high probability that AAP’s assessment of the national situation is essentially accurate for Maryland’s vaccine providers. While it may be that AAP overestimates the extent of the discontent and the likelihood that this discontent will result in significant numbers of pediatricians changing their immunization practices, the discontent is real. It may manifest itself in more subtle ways, such as earlier retirements and steering interested students away from a pediatric specialty.

If the stress, or the perception of it, becomes acute, it may show up in missed opportunities to immunize. Missed opportunities can lead to underimmunization.⁶ We can expect the same pattern if the stress grows. Whether overt or subtle, the discontent provides a challenge to the structure of immunization provision in the state. Maryland should prepare by taking measures to more precisely measure vaccination rates and by preparing the mechanisms that could more quickly respond to the results of the stress and the perception of stress.

The stakeholder interviews and the survey for this study show that Maryland’s pediatricians share the AAP’s concerns. The survey conducted interviews at 394 practices that administer pediatric vaccines. When asked to reply on a scale of one to ten, (with one being “not a burden” and ten being “a very large burden”) almost half (42.7 percent) responded with a six or higher score to the question of whether it has been a financial burden to stock and maintain adequate supplies of vaccines. Further, delays in supply caused problems delivering recommended treatment: 59.1 percent said that they have had to postpone a child’s scheduled vaccination in the past twelve months because the vaccines they would normally supply were not available from their distributors. Thirty-six percent said that they had experienced problems obtaining vaccines other than seasonal flu vaccine from vendors in the past twelve months.

The cost of new, expensive vaccines, refrigeration failures, and expired vaccines contributed to the financial burden. Almost half (41.6 percent) were “concerned” (chose a six or greater on the scale) about the risk of financial loss which could be caused by a problem with the storage of these expensive vaccines. Fifty-one (12.9 percent) had, in the past two years, discarded vaccines due to refrigeration failures and 46.4 percent had discarded expired vaccines.

Financial and management problems associated with administering vaccines from multiple sources also concerned providers. Only 217 (55.1 percent) said that their office receives adequate administration fees to cover the actual costs of administration. Of the 365 offices surveyed that had ever deal with the VFC program, 88 (24.1 percent) of them said that they are either having a “somewhat difficult” or “quite difficult” time managing both private and public vaccine supplies.

More troubling, some of Maryland’s children may not have been vaccinated because of cost concerns. Of the 394 practices surveyed, 148 (37.6 percent) stated that they did not offer certain

kinds of vaccines due to their high cost and 59 (15.0 percent) reported having had an immunization declined by a parent of an underinsured because it was too expensive "more than a few times."

It is likely that the problem is more severe in Maryland than in other states. As The Baltimore Sun reported in September of this year, "The Maryland Health Care Commission estimated that Maryland is in the bottom quarter of states nationally in how much doctors are paid for each unit of service."⁷ Our literature review has been unable to find reliable data on pediatrician compensation in Maryland. The data we did find indicated that pediatrician compensation was among the lowest specialties in medicine and that income growth in that specialty had been especially slow. Data from publicly available web sites also indicated that average compensation for pediatricians in Baltimore was lower than in comparable Eastern cities such as Philadelphia and New Haven.⁸

Better data on actual reimbursements to vaccine providers is needed and is being developed.⁹ According to Lance Rodewald, Director of the Immunization Services Division of the National Center for Immunization and Respiratory Diseases of the Center for Disease Control, as of September 2007 at least four studies were in the field that should provide more rigorous data on the extent of the problem. Maryland has established a task force to investigate physician compensation and it is possible that their studies will shed light on the stresses being put on vaccine providers.¹⁰ That task force had just begun its investigations in the fall of 2007 as this report was being written. That task force may also develop more information on the extent of the problem in Maryland. But even without such data, we conclude that there is a widespread perception within the practices of providers of vaccinations of a vaccine compensation problem, that perception is based on some established facts, and that the perception itself puts stress on the system.

The American Academy of Pediatrics (AAP) has asserted that: "Administration fee reform is essential to maintaining the medical home as the center for immunization activity. Removing the financial stress providers are currently experiencing because of large outlays of capital for vaccine inventory and inadequate payment for the service component of vaccine delivery is crucial not only to maintain but also to improve access to vaccines."¹¹ The research team has determined this assertion to be credible.

The lack of completed, formal studies, though, contributes to the research team's reluctance to recommend expensive and severe changes to the existing system for childhood vaccinations. Instead, we recommend that the state address some important needs that will also ameliorate some of the financial stresses on providers, and that it also institute changes that will position the state to better monitor the situation and take other actions when more information is available.

Implementing a universal purchase system, or making some other changes in the fundamentals of the ways vaccines are provided, has the potential to create other stresses and may lead to unpredictable consequences or difficulties. Evidence will be available in the next few years that will indicate whether the stress on the current system is so extensive that it justifies risking new stresses and difficulties. Until that evidence is gathered, the prudential course seems to be one that takes less radical steps to ameliorate the stress.

3. Challenges Facing Adult Vaccine Policy—Flu: Shortages, Inequitable Distribution and a Rapidly Changing Environment

The challenges facing adult vaccine policy are quite different. Maryland is not among the leaders in adult flu vaccination coverage rates. The production procedures for flu vaccine have resulted in sporadic shortages. Attempts to deal with these shortages have resulted in inequitable distribution patterns. However, more producers have committed to making vaccines and all indications are the 2007-2008 flu season will see much higher availability of vaccine.

3.1 Vaccine Coverage Rates for Adults in Maryland

Our research on vaccines for adults has focused primarily on annual flu and pneumonia vaccinations. Annual flu vaccination is recommended very broadly by the Advisory Committee on Immunization Practices (ACIP) for all individuals over the age of 50, higher risk younger adults, adults and children who are residents of nursing homes or other chronic care facilities, all members of households with members in the above population and all health care workers.¹² Pneumonia vaccine is recommended once for all individuals over the age of 65 and once or twice over the individual's lifespan for high risk individuals under the age of 65.

As outlined on Table 3, overall flu vaccine rates in Maryland are highest in the 65 and over age group at 66.1 percent but drop off dramatically in lower age ranges. The vaccine rate also varies by race and region of the state. For Marylanders aged 65 and over, whites are significantly more likely to have received a flu shot than blacks. This differential is also exhibited at the younger age groups, but loses its statistical significance. Marylanders in Baltimore City and Prince George's County are also less likely to have received a flu vaccine than those in other areas of the state, especially in Montgomery County, which has the highest flu vaccination rate in the state (see Table 4 on page 13).

Pneumococcal vaccine follows a similar pattern to flu in that there are both racial and geographic disparities in the pneumococcal vaccination rate (See Tables 5 and 6 on page 14).

Table 3

Maryland Behavioral Risk Factor Surveillance System, Percent of persons who reported having a Flu shot in the last year by age and race, 2006			
	Age 18 to 49	Age 50 to 64	Age 65+
	Percent with Flu Shot (95 percent Confidence Interval)	Percent with Flu Shot (95 percent Confidence Interval)	Percent with Flu Shot (95 percent Confidence Interval)
White, Non-Hispanic	23.6 percent (21.7-25.5)	42.7 (40.1-45.3)	69.4 (66.9-71.9)
Black, Non-Hispanic	21.9 (18.1-25.7)	32.5 (26.5-38.5)	52.9 (44.5-61.3)
Hispanic	21.8 (13.1-30.5)	n.a.	n.a.
Other	26.2 (19.3-33.1)	42.4 (29.9-54.9)	n.a.
Total	23.3 (21.6-24.9)	39.9 (37.6-42.2)	63.3 percent (63.9-68.8)

Source: Maryland BRFSS, www.marylandbrfss.org, data accessed: 7/30/07.

Table 4

Maryland Behavioral Risk Factor Surveillance System, Percent of persons who reported having a Flu shot in the last year by age and region, 2006			
	Age 18 to 49	Age 50 to 64	Age 65+
	Percent with Flu Shot (95 percent Confidence Interval)	Percent with Flu Shot (95 percent Confidence Interval)	Percent with Flu Shot (95 percent Confidence Interval)
Baltimore City	23.3 percent (16.8-29.8)	38.7 (29.1-48.3)	53.5 (42.2-64.8)
Baltimore Metro	23.9 (20.8-27.0)	39.8 (35.3-44.3)	68.1 (63.5-72.7)
Montgomery	28.1 (23.2-33.0)	45.4 (38.9-51.9)	73.9 (67.7-80.1)
Prince Georges	18.7 (13.3-24.1)	34.0 (25.5-42.5)	56.0 (46.1-65.9)
Eastern Shore	18.5 (15.1-21.9)	40.0 (35.1-44.9)	66.9 (62.1-71.7)
Northwest	21.4 (17.5-25.3)	38.8 (33.3-44.3)	66.0 (60.1-71.9)
Southern	21.6 (16.5-26.7)	39.9 (31.8-48.0)	65.3 (55.6-75.0)
Total	23.2 (21.5-24.8)	39.9 (37.6-42.3)	66.1 percent (63.7-68.5)

Source: Maryland BRFSS, www.marylandbrfss.org, data accessed: 8/8/07.

Table 5

Maryland Behavioral Risk Factor Surveillance System, Percent of persons who reported ever having a Pneumonia shot by age and race, 2006				
		Age 18 to 49	Age 50 to 64	Age 65+
		Percent with Pneumonia Shot (95 percent Confidence Interval)	Percent with Pneumonia Shot (95 percent Confidence Interval)	Percent with Pneumonia Shot (95 percent Confidence Interval)
White, Hispanic	Non-	10.1 percent (8.6-11.6)	19.6 (17.5-21.7)	67.5 (64.9-70.1)
Black, Hispanic	Non-	18.8 (15.0-22.6)	26.1 (20.3-31.9)	62.2 (53.8-70.6)
Hispanic		11.9 (4.6-19.2)	n.a.	n.a.
Other		19.1 (12.5-25.7)	16.6 (6.8-26.4)	n.a.
Total		13.7 (12.3-15.1)	21.2 (19.2-23.1)	66.2 percent (63.7-68.7)

Source: Maryland BRFSS, www.marylandbrfss.org, data accessed: 7/30/07.

Table 6

Maryland Behavioral Risk Factor Surveillance System, Percent of persons who reported ever having had a Pneumonia shot in the last year by age and region, 2006				
		Age 18 to 49	Age 50 to 64	Age 65+
		Percent with Pneumonia Shot (95 percent Confidence Interval)	Percent with Pneumonia Shot (95 percent Confidence Interval)	Percent with Pneumonia Shot (95 percent Confidence Interval)
Baltimore City		17.8 percent (11.6-24.1)	25.5 (16.8-34.3)	66.1 (55.2-77.0)
Baltimore Metro		12.4 (9.8-15.0)	19.0 (15.3-22.7)	67.8 (63.1-72.7)
Montgomery		11.1 (7.4-14.8)	20.4 (14.9-25.9)	67.7 (60.9-74.5)
Prince Georges		20.6 (14.8-26.5)	25.3 (17.2-33.5)	53.2 (43.1-63.3)
Eastern Shore		14.9 (11.6-18.2)	23.0 (18.7-27.3)	67.4 (62.6-72.2)
Northwest		9.6 (6.6-12.6)	22.3 (17.5-27.1)	68.0 (62.1-73.9)
Southern		10.3 (6.3-14.3)	17.9 (11.4-24.4)	68.3 (58.8-77.8)
Total		13.7 (12.3-15.1)	21.2 (19.2-23.2)	66.0 percent (63.6-68.5)

Source: Maryland BRFSS, www.marylandbrfss.org, data accessed: 8/8/07.

3.2 The Potential Cost of Buying Flu Vaccine for all Marylanders

Maryland's population as of 2006 is estimated by the American Community Survey (ACS) conducted by the U.S. Census Bureau to be approximately 5,615,727 persons. Completely vaccinating the entire population with flu vaccine, assuming universal coverage, complete take-up for recommended parties, and no vaccine wastage, could cost between \$67 million and \$77 million dollars, depending on the rate that the state was able to negotiate with vaccine manufacturers. The lower estimate reflects the lower negotiated CDC rate and the higher estimate is the current private vaccine price. If the state were to purchase such a large quantity of vaccines, it is reasonable to assume that manufacturers would be willing to negotiate a lower price than the private price. However, the price may not be as low as the CDC price since that price was negotiated on behalf of uninsured and underinsured children. Furthermore, this cost estimate assumes use of the injectable flu vaccine. If the FluMist® is used, the cost per spray ranges from \$17.65 to \$17.95 per dose, increasing costs for the percentage of vaccines that is administered through this mechanism. FluMist has been approved for persons age 2 through 49.

These cost estimates are costs of the vaccine only, and not administration, storage or other costs associated with delivery of the vaccine (See Table 7 on page 16).

Table 7

Estimate of Cost of Public Purchase of Flu Vaccine for all of Marylanders					
ACS Demographic and Housing Estimates 2006 ^a	Estimate ^a	CDC Flu Vaccine Cost/Dose Approximate Average Cost ^b	Flu Vaccine Private Sector Cost/Dose Approximate Average Cost ^b	Lower Estimate to Purchase Flu Vaccines for Entire Maryland Population ^c	Upper Estimate to Purchase Flue Vaccines for Entire Maryland Population ^c
Total Population in Maryland	5,615,727	\$12.03	\$13.78	\$67,557,195	\$77,384,718
Population of Persons Age 18 to 64	3,606,263				
Estimate of Underinsured (30 percent) age 18 to 64	1,081,879	\$12.03	\$13.78	\$13,015,004	\$14,908,292
Estimate of Uninsured Adults age 18 to 64 2003 ^d	700,000	\$12.03	\$13.78	\$8,421,000	\$9,646,000
Estimate of Combined Uninsured and Underinsured Adult Population	1,857,879	\$12.03	\$13.78	\$22,350,284	\$25,601,572

- a. Source: U.S. Census Bureau, 2006 American Community Survey, http://factfinder.census.gov/servlet/ADPTable?_bm=y&-geo_id=04000US24&-qr_name=ACS_2006_EST_G00_DP5&-ds_name=ACS_2006_EST_G00_-lang=en&-sse=on, accessed September 24, 2007.
- b. Source: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>, accessed August 1, 2007.
- c. Source: Author's calculations.
- d. http://www.mdpolicy.org/docLib/20060117_PolicyReport20062.pdf, accessed September 24, 2007.

As discussed under challenges, above, 30 percent of the adult Maryland population does not have insurance coverage for immunizations and another 13 percent have no health insurance

whatsoever. Since nearly half of the population has no coverage, if Maryland decided to purchase flu vaccines for the uninsured and underinsured population in Maryland, the cost to the state would be between approximately \$22 and \$26 million dollars (See Table 7). This assumes that vaccine was purchased for all under and uninsured individuals.

The state would not be able to recoup insurance company costs from the uninsured persons, but perhaps would be able to get a contribution from the insurance programs which insure the underinsured population of the state. As before, these cost estimates are costs of the vaccine only, and not administration, storage or other costs associated with delivery of the vaccine.

4. Challenges Facing Adult Vaccine Policy—HPV: Unanswered Questions, Timing, and Logistical Barriers

One alternative suggested was to finance the purchase of HPV vaccine for adults. HPV vaccine is already provided for eligible children through the VFC program. The research team reviewed the literature with this alternative in mind. Our findings are presented in this section.

Since HPV reporting is not required, the level and trends for HPV infections must be estimated. For people ages 14 to 44, an estimated 6.2 million annual incident cases of HPV infection occur, three-quarters in those aged 15-24.¹³ A Markov model estimates a woman's lifetime cervical cancer risk of 3.67 percent and a lifetime cervical cancer mortality risk of 1.26 percent.¹⁴

Human papilloma virus (HPV) is a predominantly sexually-transmitted disease, with greater risk associated with increases in the lifetime number of sexual partners, though risk appears higher during the first 10 years of sexual activity. Mother to child transmission during childbirth has also been reported, though it is a less common route of transmission. HPV consists of more than 100 types of the virus - 40 in the genital region.¹⁵ An estimated 10 percent of infections progress to a pre-cancerous stage and a minority of those over decades develop to cancer.¹⁶ The carcinogenic or high-risk types that have been identified are 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 73, and 82.¹⁷ Two types, HPV-16 and HPV-18, account for 70 percent of cervical cancer cases globally¹⁸ – though many women infected with high-risk HPV type do not develop cervical cancer.¹⁹ As illustrated in Table 8 (Table 1 in the original)²⁰, although discussions focus on cervical cancer, HPV poses risks for other anatomic sites and for males.

Table 8

TABLE 1. Cancers associated with human papillomavirus (HPV) and percentage attributable to oncogenic HPV — United States, 2003

Cancer	Cases*	% Attributable to oncogenic HPV†
Cervix§	11,820	100
Anus¶	4,187	90
Vulva¶	3,507	40
Vagina¶	1,070	40
Penis¶	1,059	40
Oral cavity and pharynx¶	29,627	≤12

*Source: U.S. Cancer Statistics Working Group. United States cancer statistics: 2003. Incidence and mortality. Atlanta, GA: US Department of Health and Human Services, CDC, and the National Cancer Institute; 2006. Available at <http://www.cdc.gov/uscs>.

†Source: Parkin M. The global health burden of infection-associated cancers in the year 2002. *Int J Cancer* 2006;118:3030–44.

§A total of 70% attributed are HPV types 16 or 18.

¶Majority of these cancers attributable to HPV type 16.

Source: MMWR March 23, 2007 / 56(RR02); 1–24 2007.

Following an expedited review, on June 8, 2006 the United States Food and Drug Administration approved Gardasil[®]; a quadrivalent HPV vaccine (types 6, 11, 16, 18) manufactured by Merck and Company, for women aged 9 to 26. The manufacturer agreed to post-marketing studies of long-term effectiveness and safety, which will provide additional information on the appropriate recommendations and use of the vaccine.²¹ Gardasil[®] is administered in three doses: initial injection, then at 2 months and then at 6 months.

A vaccine's appeal is that it requires less behavioral modification and might prevent serious sequelae, unlike a mechanical barrier such as a condom. Use of a condom lowers the rate of infection with the human papilloma virus, it does not eliminate it. A study of healthy undergraduate women aged 18 to 22 years *who had never had vaginal intercourse or had first had intercourse with one male partner within the previous three months* examined the potential protection provided by condom use. Among women who reported that their partners used a condom 100 percent of the time during the eight months prior to being tested, there were 37.8 genital HPV infections per 100 patient-years at risk compared with 89.3 infections for those who reported partners who used condoms less than 5 percent of the time.²² Of the numerous HPV types, the difference based on partner condom use was consistently seen between carcinogenic or high-risk (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 73, and 82)²³ and low-risk (6, 11, 40, 42, 54, 55, 57, 61, 62, 64, 69, 70, 71, 72, 81, 83, 84, and CP6108) types and the quadrivalent types (6, 11, 16, and 18).²⁴

The vaccine has been demonstrated to have a high efficacy against HPV types for which it is marketed. Based on assumptions of complete vaccination of girls at age 12 and duration of vaccine efficacy (currently reported for 60 months but longer trials are ongoing) 20 to 66 percent of cervical cancer cases could be prevented.²⁵

As noted in an editorial accompanying an HPV-focused issue of the *New England Journal of Medicine*, cervical cancer; 1) can be caused by more than the two high-risk types studied (HPV-16 and HPV-18) – though they are responsible for a high proportion of cervical cancers, and 2) can only be prevented if vaccination occurs prior to infection.²⁶ A report in the Canadian Medical Association estimated the number of girls aged 12 needed to be vaccinated to prevent one case of genital warts as 8 and to prevent one case of cervical cancer as 324. If, however, vaccine efficacy decreases over time, say 3 percent per year, then these estimates increase to 14 and 9,080.²⁷

ACIP recommends the three vaccination sequence for females aged 11-12 with consideration of girls down to 9 years of age and catch-up vaccination for women 13-26 (see Figure 1 on page 20). However, the American Cancer Society does not recommend vaccinating all women between the ages of 18 and 26 since an increase in the number of sexual partners would be expected (see Figure 2 on page 21).²⁸

Specific information gaps or concerns identified by ACIP include:²⁹

- **Duration of Protection from the Quadrivalent Vaccine:** Long-term data on duration of antibody response and clinical protection will be obtained through studies conducted in the Nordic countries through the Nordic cancer registries and through other studies in the United States. Follow up of vaccine trial participants aged 9-15 years will continue for up to 10 years after dose 3. This will include evaluation of antibody titers and, in participants who reach their 16th birthday, evaluation of vaccine effectiveness.
- **Surveillance for HPV-Related Outcomes:** Although it will take years to realize the impact of vaccination on cervical cancer, decreases in cervical cancer precursors and genital warts should be realized sooner. Studies are planned to monitor these lesions and other HPV-related outcomes in the United States.
- **Virologic Surveillance:** Prevalence and incidence of HPV types in the vaccine are expected to decrease as a result of vaccination. Studies are planned to monitor HPV types in various populations and specimens.
- **Safety of Vaccination:** Postlicensure studies to evaluate general safety and pregnancy outcomes will be conducted by the manufacturer and independently by CDC. Monitoring will be accomplished through VAERS and CDC's Vaccine Safety Datalink, which will include surveillance of cohorts of recently vaccinated females and evaluation of outcomes of pregnancy among those pregnant at the time of vaccination. The manufacturer will be monitoring long-term safety as part of the Nordic Cancer Registry Program.
- **Simultaneous Vaccination:** Safety and immunogenicity studies of simultaneous administration of quadrivalent HPV vaccine with Tdap and MCV4 are ongoing.
- **Efficacy of HPV Vaccine in Men:** Studies are needed to define the efficacy of HPV vaccination in preventing genital warts and anogenital intraepithelial neoplasia in men. Studies of the effectiveness of HPV vaccination of men in preventing transmission to both female and male sex partners are also needed.
- **Cervical Cancer Screening:** Recommendations for cervical cancer screening guidelines have not changed. Evaluation of the impact of HPV vaccination on cervical cancer

screening provider practices and women's screening behavior is needed as well as further economic analyses.

- **Vaccine Delivery and Implementation:** Administration of 3 doses of vaccine in adolescents will be challenging. Programmatic research is needed to determine optimal strategies to reach this age group

The rarity of cervical cancer, the additional sources of HPV infection not covered by the existing approved vaccine nor in the most prominent vaccine now in clinical research, the unanswered questions regarding long-term safety and use of the approved vaccine, and the importance of vaccination prior to sexual debut, are among the findings that lead us not recommend universal purchase of HPV vaccines for adults at this time.

There is a further logistical barrier to state purchase of vaccines for adults. It would take significant amounts of time and money to plan and to build an infrastructure to distribute vaccines to adults and to provide quality control. With children's vaccines it is assumed that the provider system now used for the VFC program could be adapted and expanded to provide the infrastructure needed for a new program. This cannot be assumed for adult vaccines. One recent article the current situation this way, "the public sector plays little role in actually administering immunizations to adults, nor a quality assurance role to improve vaccination performance of adult immunization providers."³⁰

State action at this time might also preempt private market action. Merck sponsors a Vaccine Patient Assistance Program that helps provide vaccines produced by Merck (which includes vaccines for HPV, MMR, PPV23, hepatitis B, hepatitis A, varicella, and zoster) to some individuals 19 and older. To qualify these individuals must reside in the United States, not have health insurance and have an annual income less than \$20,240 for an individual, \$27,380 for couples, or \$41,300 for families of four. Others with hardships may qualify as well.³¹

Figure 1. ACIP Recommendations for Use of HPV Vaccine

Recommendations for Routine Use and Catch-Up

Routine Vaccination of Females Aged 11--12 Years

ACIP recommends routine vaccination of females aged 11--12 years with 3 doses of quadrivalent HPV vaccine. The vaccination series can be started as young as age 9 years.

Catch-Up Vaccination of Females Aged 13--26 Years

Vaccination also is recommended for females aged 13--26 years who have not been previously vaccinated or who have not completed the full series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, females who might have already been exposed to HPV should be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types would receive full benefit from vaccination. Vaccination would provide less benefit to females if they have already been infected with one or more of the four vaccine HPV types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk for HPV infection might continue as long as persons are sexually active. Pap testing and screening for HPV DNA or HPV antibody are not needed before vaccination at any age.

Recommended Schedule

Quadrivalent HPV vaccine is administered in a 3-dose schedule. The second and third doses should be administered 2 and 6 months after the first dose.

Cervical Cancer Screening Among Vaccinated Females

Cervical cancer screening recommendations have not changed for females who receive HPV vaccine (Table 2). HPV types in the vaccine are responsible for approximately 70 percent of cervical cancers; females who are vaccinated could subsequently be infected with a carcinogenic HPV type for which the quadrivalent vaccine does not provide protection. Furthermore, those who were sexually active before vaccination could have been infected with a vaccine type HPV before vaccination. Health-care providers administering quadrivalent HPV vaccine should educate women about the importance of cervical cancer screening.

Groups for Which Vaccine is Not Licensed

Vaccination of Females Aged <9 Years and >26 Years

Quadrivalent HPV vaccine is not licensed for use among females aged <9 years or those aged >26 years. Studies are ongoing among females aged >26 years. No studies are under way among children aged <9 years.

Vaccination of Males

Quadrivalent HPV vaccine is not licensed for use among males. Although data on immunogenicity and safety are available for males aged 9--15 years, no data exist on efficacy in males at any age. Efficacy studies in males are under way.

Figure 2 Summary of American Cancer Society (ACS) Recommendations for Human Papillomavirus

(HPV) Vaccine Use to Prevent Cervical Cancer and Its Precursors

- Routine HPV vaccination is recommended for females aged 11 to 12 years.
- Females as young as age 9 years may receive HPV vaccination.
- HPV vaccination is also recommended for females aged 13 to 18 years to catch up missed vaccine or complete the vaccination series.
- There are currently insufficient data* to recommend for or against universal vaccination of females aged 19 to 26 years in the general population. A decision about whether a woman aged 19 to 26 years should receive the vaccine should be based on an informed discussion between the woman and her health care provider regarding her risk of previous HPV exposure and potential benefit from vaccination. Ideally the vaccine should be administered prior to potential exposure to genital HPV through sexual intercourse because the potential benefit is likely to diminish with increasing number of lifetime sexual partners.
- HPV vaccination is not currently recommended for women over age 26 years or for males.
- Screening for cervical intraepithelial neoplasia and cancer should continue in both vaccinated and unvaccinated women according to current ACS early detection guidelines.

*Insufficient evidence of benefit in women aged 19 to 26 years refers to (1) clinical trial data in women with an average of 2, and not more than 4, lifetime sexual partners, indicating a limited reduction in the overall incidence of cervical intraepithelial neoplasia (CIN)2/3; (2) the absence of efficacy data for the prevention of HPV16/18-related CIN2/3 in women who have had more than 4 lifetime sexual partners; and (3) the lack of cost-effectiveness analyses for vaccination in this age group.

4.1 Existing Purchasing Systems in the United States for Adults' Vaccines

Vermont recently conducted a short study of Universal purchasing options and concluded that the "purchase of vaccines for adults is totally within the private sphere." This is not quite true, but describes the general situation. An earlier investigation into universal vaccine purchasing systems, the Rutgers report (whose primary author, Sandra Howell-White, is also a member of our research team), found that Massachusetts does provide "approximately half a million doses of TD and influenza vaccine." Massachusetts also offers pneumococcal polysaccharide immunizations and Hepatitis A and B vaccines at some specific sites." The Rutgers report also found that Alaska provides adults with tetanus, pneumococcal, and influenza vaccines.³²

In writing of the current system for adults, the Vermont report stated:

Purchases are made in two ways, the physician purchases the amount of vaccine he or she estimates will be needed for the patient population, or writes a prescription for the vaccine which the patient has filled at a local pharmacy and brings to the office for

vaccine administration. With the increasing number and cost of vaccines, fewer providers are able to purchase all the needed vaccines up front, leading to more prescriptions being written.

Vaccine prices can vary widely with the federal contract for the VFC program having some of the lowest costs, while higher costs for other large purchases such as the Minnesota Multi-State Purchasing Agreement and the highest prices are for individual doses on the retail market (at pharmacies). As an example, vaccines to prevent meningitis cost \$68 per dose from the CDC contract and \$81 per dose from the Multi-State contract. The actual retail price in Vermont is \$105 or more per dose.³³

The CDC requires that grantees use at least 2 percent of their funds on adult immunization practices. Furthermore, Medicare is a primary financing source for vaccinations in the 65 and over, disabled and end-stage renal disease populations. Beyond these two programs, public financing for adult vaccinations is relatively underutilized. Some states have programs which purchase vaccines for adults through specialized outreach programs; however, these states tend to be the exception.³⁴

4.2 Description of Some of the Challenges for Adult Vaccine Policy

The challenges facing the state in the matter of adult vaccine policy are also real, but here, past experience is not a reliable foundation on which to build new policy. The environment in this area is quickly changing. Although some inconsistencies in Flu vaccine production are likely to remain, the general increase in supply and uptake of the vaccines will create different challenges.

One primary challenge for adults involves access to influenza vaccines. Researchers report that 36,000 people in the U.S. die from the flu each year, with another 200,000 hospitalized due to the flu. Demand has increased for the flu vaccine due to a combination of publicity and public education efforts. While Maryland has increased the number of flu vaccinations each year, significant problems remain with this system.

According to the 2007 Annual Social and Economic Supplement of the CPS, in Maryland there are 776,000 persons or 13.8 percent of the population without health insurance.³⁵ Of those with private insurance, many are considered underinsured in that they do not have immunization coverage as part of their private insurance. While the exact number of individuals without vaccination coverage is very difficult to ascertain, the IOM estimates that more than 30 percent of privately insured adults age 18 to 64 do not have vaccination coverage.³⁶

In addition to problems related to payment, due to a lack of coverage in the past few years, vaccine supply has arrived late or in staggered lots that mean that supply is not available to meet demand.³⁷ Vaccine creation is a nine month process with each batch requiring certification that can result in underproduction if something goes wrong with the production process. According to a recent article on Maryland's flu vaccine supply from 2001-2004, several factors have created this problem. First, most suppliers target their vaccine for delivery in November and demand appears to peak in September and October, before supplies are available. Problems with production lead to too few dosages arriving when needed, leading ultimately to a combination of inability to meet initial demand, some over pricing, and unused supply at the end of the flu season due to supplies arriving after demand peaks. For example, in 2001-2002, 18 percent of Maryland health jurisdictions reported surplus flu vaccine at the end of the season. Newly

approved nasal vaccines are particularly prone to oversupply, with 63 percent of Maryland health jurisdictions reporting oversupply of nasal vaccine in 2004-2005.³⁸

Delivery problems are encountered as a result of the nature of the flu vaccine delivery chain. Vaccines are delivered through two mechanisms, with about half of the vaccine delivered directly to retail outlets, pharmacies, hospitals, public health offices and other customers while the other half is delivered through distributors to physicians' offices and clinics. This distribution system causes problems because some providers may have trouble getting sufficient vaccine while others may receive too much. On a more positive note, this bifurcated delivery system means that more venues are now administering the vaccine. While the majority of patients still prefer to receive vaccinations from their doctors rather than a retail store or public health clinic, increasingly retail outlets are becoming an alternative to the overburdened physician system. For example, while 59 percent of patients aged 18-48 preferred to receive their flu vaccination from their doctor, only 46 percent actually used this site to obtain a vaccination. This held true for older age groups as well. Ten percent of adults ages 18-49 and 11 percent of the elderly obtained vaccinations from a retail store. While retail outlets are now a small part of the vaccine delivery system, they represent a growth venue that could potentially relieve some of the stress on the increasingly strained physician offices.³⁹

These instabilities and changes create problems. A medical practice must estimate its flu vaccine needs early in the year. If the vaccine is late in arriving, patients that were expected to be available for vaccination in October or November may not be available later in the season or may receive a vaccination in some other venue. In allocating the early shipments of vaccines some manufacturers ship to a venue a percentage of what was used in the prior year. This system, if continued over time, would leave smaller practices, the practices that are more likely to lose market share because of late shipments, with a continuously shrinking percentage of the vaccines shipped.

These problems are illustrated by the results of our survey. Of the 282 practices that had answered the question by September 27, 144 (51.1 percent) said that they have experienced difficulties in obtaining annual flu vaccine for the practice. One hundred and fifteen practices (40.8 percent) said that they have had to refer patients to other providers to get flu shots. Of the 115 who had to refer patients away, 87.8 percent said it was because they were unable to get enough vaccine from suppliers in a timely manner.

We also asked questions about possible solutions to the problem. We asked "If the state of Maryland guaranteed that it would buy back unused flu vaccine at 75 percent of what you paid for it, would you likely increase the amount of flu vaccine that you typically order? A large majority of the respondents (64.5 percent) said they would increase the amount of flu vaccine that they would typically order. Of the 282 practices that answered the question, 190 (67.4 percent) said they think that such a buy-back program would help them manage their flu vaccine inventory more effectively.

Despite these difficulties, Maryland has developed strategies to improve delivery and communication by local health departments working in partnership with the DHMH and the Maryland Partnership for Prevention.⁴⁰ However, delivery challenges will remain because the demand for flu vaccine is rapidly increasing, with the Health Industry Distributors Association

reporting that the global market for vaccine is expected to grow 13.2 percent per year through 2012.⁴¹

Whether these allocation problems will persist in a new environment of higher production of vaccine is a question that we cannot answer at this time. HIDA reported that 120.9 million doses of flu vaccine were produced last season, compared to approximately 88.3 million doses in other recent seasons.⁴² This year the American Medical Association's Influenza Vaccine Availability Tracking System (IVATS) reported as of September 26th that "A record number of 132 million doses of influenza vaccine have been projected for the 2007-2008 influenza season. With this more-than-ample supply anticipated, the objective is that influenza vaccination occurs until vaccine is no longer available."⁴³

5. Challenges to developing adequate new policies—the uninsured and the underinsured

According to the 2007 Annual Social and Economic Supplement of the CPS, in Maryland there are 776,000 persons or 13.8 percent of the population without health insurance.⁴⁴ Of those with private insurance, many are considered underinsured in that they do not have immunization coverage as part of their private insurance. While the exact number of individuals without vaccination coverage is very difficult to ascertain, the IOM estimates that more than 30 percent of privately insured adults age 18 to 64 do not have vaccination coverage.⁴⁵

The underinsured children in Maryland have been better served. The Journal of the American Medical Association (JAMA) printed an article in the August 8, 2007 issue entitled "Gaps in vaccine financing for underinsured children in the United States."⁴⁶ The authors of this article had examined programs throughout the United States. In a telephone interview Grace Lee, the lead author, indicated that Maryland was not one of the states of concern about such gaps.

One reason for Maryland's progress in the area of vaccine provision to the underinsured is that Maryland is one of the states that have extended most fully the possibilities in the federal program known nationally as the State Children Health Insurance Programs (SCHIP). Maryland's version of this program MCHIP extends insurance coverage to some children whose families have income up to 300 percent of poverty.

Maryland also has fewer underinsured children because the state mandates that the deductibles in insurance companies' policies do not apply to children's vaccines. Provisions for co-payments are not so restricted.

6. Challenges to Developing Adequate New Policies—ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) has two clauses that are in substantial conflict with each other. As Justice Souter put it in his Opinion of the Court in *Rush Prudential HMO v Moran*, "ERISA sets 'minimum standards ... assuring the equitable character of such plans and their financial soundness,' . . . and contains an express preemption provision that ERISA 'shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan ...'. A saving clause then reclaims a substantial amount of ground with its provision that 'nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.' The 'unhelpful' drafting of these antiphonal clauses . . . occupies a substantial share of this Court's time."

In practice this means that any new regulation regarding insurance must be carefully drafted and may be more or less subject to challenge in Federal courts. The key seems to be, to quote Justice Scalia's opinion of the Court in *Kentucky Association of Health Plans v Miller* "laws that regulate *insurance*, not insurers" are saved from ERISA preemption.

This can be especially problematic for Maryland. Using data from the 1993 National Employer Health Insurance Survey on 34,604 private sector establishments, Park estimated the percent of firms in each state that self-insure and the percent of employees within each state that are covered under self-insured plan. These estimates are important because these firms are exempt from state regulation of health insurance benefits. In Maryland, 20.2 percent of employers self-fund their health insurance and provide insurance to 49.1 percent of employees working in Maryland. Although these estimates are somewhat dated, the trend has been for more employers to self-insure and in that way may be viewed as a lower estimate of the number of employers and employees affected. (Source: Christina H. Park, Prevalence of Employer Self-Insured Health Benefits: National and State Variation. *Medical Care Research and Review*, Vol. 57 No. 3, (September 2000) 340-360.)

Given that not much about ERISA can be said with certainty, the research team believes that, with careful drafting, some new policies that regulated health insurance could be successfully implemented. Others are less likely to be successful. Where relevant, we discuss the possibilities as we investigate the options in the sections below.

7. Challenges to Developing Adequate New Policies—the Possibility of National Policy Changes

As this study was being conducted, national policy changes in programs related to immunizations were being contentiously debated in Washington and on the presidential campaign trails. Some of the policies that have been proposed might be better planned in a more certain environment. New rules have been proposed that would restrict Maryland from using the MCHP program to cover as many children as it currently does. Some legislative proposals would allow the expansion of SCHIP programs.

8. Challenges to Developing Adequate New Policies—Planning for Crisis Situations

There appears to be consensus that more needs to be done to make the immunization delivery system better able to function in crisis situations. Pandemics, natural disasters, and terrorist attacks are events that may call for changes in immunization delivery systems. They are also events where the benefits of an immunized population and information about immunizations could be very high. When considering new policies, the resulting effects on these crisis situations should be a priority.

9. Challenges to Developing Adequate New Policies—the Current Inadequacy of Maryland’s Immunization Reporting System

Since 1993, states have received funding to maintain registries of vaccinations called Immunization Information Systems (IIS). These registries appear extremely cost effective. While the projected annual cost of the nationwide IIS for children 0-6 is \$100 million, the system would save an estimated \$280 million per year.⁴⁷

Cost savings come from a combination of simplified immunization assessment activities for schools (\$168 million), less need to manually pull vaccination records as children enter kindergarten (\$58 million), less need to provide paper records when changing physicians (\$16.2 million), fewer duplicate immunizations (\$26.5 million), simplifying health plan employer data and information set reports (\$2 million), and reducing data collection for the National Immunization Survey (\$11.1 million).

The IIS are expected to improve immunization rates for vulnerable populations as well as enhance public health by providing data for infection control. However, while reports for Oregon show that registries improved immunization rates by roughly one-third, other states show little improvement after the registry was instituted.⁴⁸ They may also prove useful in disaster situations.

Maryland has a voluntary system of immunization registration called “ImmuNet” which assists in vaccine management and consolidates immunization records. Unfortunately, the current system of recording and reporting immunizations is inefficient and creates high and avoidable costs for Maryland citizens. It is not used widely by providers. Currently 217 provider offices are using this service for over one million patients and over seven million immunizations;⁴⁹ however, this is a small proportion of Maryland providers. In 2000, the CDC reported that Maryland had 744 VFC provider sites (676 private providers and 68 public providers).⁵⁰ Among the interviewed practices that offer childhood vaccines, 71.6 percent never or rarely used it, while only 25.9 percent stated that they always or sometimes use the registry. Similarly, 70.6 percent of practices indicated that they rarely or never use it to find past immunization records when a child transfers to their practice, while 27.4 percent stated that they always or sometimes use it for such a purpose.

Despite the lack of ImmuNet’s use, there were few who reported problems using the system and nearly two-thirds (65.7 percent) of respondents reported that they believed integrating the registry with vaccine ordering would be useful. When asked to rank their support of a mandatory registry for Maryland, slightly more than one-half (53.8) responded with a six or more, and approximately 75 percent of them with a ten, on a scale from one to ten (one being not at all supportive and ten being very supportive). The extra cost related to a mandatory electronic immunization registry system would, however, be a problem for one-third (35.0 percent) of all the respondents who provide childhood immunizations.

The current system of recording and reporting immunizations is inefficient and creates high and avoidable costs for Maryland citizens. A stronger system would provide an early warning

system that identifies when stresses in the system start affecting immunization rates in specific populations. It would allow prompt and reliable measures of the impact of policy changes. The lack of such a system presents a challenge in developing new policies.

10. Perceptions of Problems with Providing Pediatric Vaccines

Discussion of problems with pediatric vaccine costs and delivery earlier in this report revealed that many providers are concerned about the vaccine purchase, storage, and delivery system (see pages 9 and 10 above). Providers also expressed concern that increasing costs would limit their ability to provide vaccinations. Of the 394 practices who indicated that they administered pediatric vaccines, 148 (37.6 percent) said that the high cost of some vaccines caused their office to refrain from offering certain kinds of vaccinations to patients. Of those 233 practices, 86 (37.0 percent) said that they have had to postpone childhood vaccinations more than a few times in the last twelve months. Fifty-nine (15.0 percent) of 394 respondents said that their practice has (more than a few times or often) been faced with and underinsured patient who declines an immunization because it is too expensive.

Financial losses loomed large in survey respondent concerns. On a scale of one to ten, (one being not at all concerned and ten being very concerned), 164 (43.9 percent) of the 374 respondents were on the concerned side (six or greater) about the risk of financial loss which could be caused by a problem with the storage of these expensive vaccines.

As noted earlier in this report, providers reported experiencing problems obtaining vaccines from vendors when they were needed. Of the 143 practices who responded "yes" to experiencing problems obtaining vaccines when needed, 114 practices had issues obtaining the varicella vaccine and 79 practices had trouble with the PCV 7 vaccine.

11. Perceptions of Problems with Providing Influenza Vaccines

From all of the respondents (422) to this survey, 208 (49.3 percent) indicated that they have experienced difficulties in obtaining annual flu vaccines for their practice. When asked if the respondents have had to refer patients to other providers to get flu shots, 172 (40.8 percent) indicated that they have. If the state of Maryland guaranteed that it would buy back unused flu vaccine at 75 percent of what was paid for it, 248 (58.8 percent) of 422 respondents indicated that they would increase the amount of flu vaccine that they would typically order. Of the 422 practices surveyed, 266 (63.0 percent) said they think that such a buy-back program would help them manage their flu vaccine inventory more effectively.

12. Provider Support for Changes

The respondents in the survey overwhelmingly would support a system where the state of Maryland would buy and distribute all the required children vaccines (not just VFC children). From a scale of one to ten, (one being not at all supportive and ten being very supportive), 281 (73.2 percent) answered with a ten. Only 12.7 percent were not supportive (five or less) of Maryland buying and distributing all children's vaccines. Of the 394 respondents, 248 (63.0

percent) of respondents said that they thought that such a program would help increase the number of children in their practice who are immunized in a timely manner. But 30.1 percent of the practices (who stated yes or no) indicated that administration fees would still be a problem with the above change; while 63 percent of those individuals said it would only be a minor problem.

13. Provider Perceptions of the Immunization Registry

When asked how often their practice used the state's registry (ImmuNet), 71.6 percent said that they never or rarely used it, while 25.9 percent stated that they always or sometimes used the registry. Similarly, 70.6 percent of practices indicated that they either rarely or never use ImmuNet to find past immunization records when a child transfers to their practice, while 27.4 percent stated that they always or sometimes use ImmuNet for such a purpose.

Only 26 (6.6 percent) reported ever having had a problem with the registry and 259 (65.7 percent) said that such a registry that was integrated with vaccine ordering would be useful. The extra cost related to a mandatory electronic immunization registry system was indicated to be a problem by 138 (35.0 percent) respondents. When asked if people would be supportive of Maryland establishing a mandatory electronic registry on a scale from one to ten (one being not at all supportive and ten being very supportive), 212 (53.8 percent) indicated that they were on the supportive side (six to ten), with 162 (41 percent) indicating a ten.

Section 4: Specific Findings about Suggested Options for Purchase and Delivery Systems in Maryland

In undertaking our task of studying "all available options for the purchasing of vaccines, including the development of a universal vaccine purchasing system, or a similar program to increase access to necessary vaccines, for the state," we used the literature and the stakeholder and expert interviews to identify options. In this section we present some of the information specific to these options.

We begin by examining the universal vaccine purchasing system and the universal *select* vaccine purchasing system. These options, if found viable, have the potential to, at least partially, address many of the vaccine policy challenges for children and adults.

1. Specific Findings Related to Universal Vaccine Purchasing

A universal vaccine purchasing system is defined by the CDC to be a system that "Through a combination of VFC, 317 and state funding, the immunization project supplies ALL routinely recommended pediatric vaccines to all public and private VFC enrolled providers to vaccinate all children in the project area." A universal select system is defined as a system that "through a combination of VFC, 317 and state funding, the immunization project supplies all, but a few, routinely recommended pediatric vaccines to ALL public and private VFC enrolled providers to vaccinate all children in the project area." These options, if found viable, have the potential to, at least partially, address the challenges both of the children's vaccine policy and adult's

vaccine policy. We talked to officials in other states who administer such programs to learn more about the potential and the weaknesses of such programs. The findings from each of these states are discussed below. Then we discuss the preliminary regression analysis findings from the NIS, the preliminary cost analysis and the alternative financing arrangements.

To evaluate the potential for Maryland to develop a Universal Vaccine Purchasing System, those states that have a universal or a universal select system or we had found had strongly considered universal status were targeted first for interviews regarding how they structure, implement, and finance their systems. The interviews included open-ended questions about the Universal Vaccine Purchasing System program, its structure, implementation, and cost. Specifically, we asked how these programs operated, how they distributed the vaccines, if they had a registry and if so how it operated, how they are financed, challenges to the system, and lessons and/or advice they might offer to other states interested in creating a Universal Vaccine Purchasing System.

Connecticut

Connecticut is a universal select state that focuses mostly on children 0-18. They provide some adult vaccines (Hepatitis A & B) to clinics that focus on sexually transmitted diseases. Until 2000, Connecticut was a universal state but lack of funds for the new vaccine costs (such as Prevnar, Hepatitis A, Roto virus, and HPV) required that they move to a select status. The program staff would like to return to being a universal state, and are trying to persuade the legislature to appropriate state dollars. They are trying to demonstrate the long-term money savings; however, they have a revenue neutral system (July through June). The program receives 9 million in state dollars, but would need 27 million to fund a universal program.

Currently, they fund the system with VFC, state and 317 monies. They purchase their vaccines through the federal contract. This is a point of contention with the manufacturers that feel vaccines purchased under federal contract should only go for VFC kids. The state does collect money from insurance companies for privately insured children. To do this, the commission of public health and insurance, have formulated a tax based on the number of children within each insurance company. However, there is a mandate to remain under a cap. The tax is based on 100 percent of the children getting vaccine coverage.

Connecticut is in the process of transitioning their distribution system over to McKesson (http://www.mckesson.com/en_us/McKesson.com/) as requested by the CDC. McKesson will do all the distribution. The state is not sure if this will provide a cost savings given the shipping costs. Additionally, there have been some start-up issues. At present, providers fax their orders to the state on a monthly basis. Providers are asked to report over-supply so the state can transfer the vaccines.

Connecticut also has a mandatory immunization registry which is separate from the ordering system. Providers report all immunizations using a paper system. They are moving toward a web-based system modeled after the Michigan system but tailored to Connecticut's needs. No financial incentives are to be given to providers, but they do give out small tokens such as

plaques, certificates, and coffee cakes. They feel the system has good reliability, and broad scale training will be provided after piloting the system.

Several concerns are that providers feel inundated from all sides, and are not happy about the lack of money for vaccines such as HPV, and about the low administration fees. Program staff feels the insurance companies are not receptive to expanding the program, because they are not seeing the cost savings even though they only have to reimburse the administration fee, which is cheaper than reimbursing the providers who would otherwise be purchasing the vaccines privately.

In terms of recommendations for Maryland, Connecticut advises that Maryland "keep moving forward, with costs rising, and more vaccines, even if you make small steps, better for the kids, to have a plan."

Idaho

Idaho's Universal Vaccine Purchasing System has existed since the CDC started the VFC program in the 1990s. They hope to remain a universal vaccine purchase state, but are currently listed as a select state because they weren't sure if they could fund HPV. They have offered this vaccine to the public providers, and are looking for the funding from their legislature for the private ones. New vaccines have stressed the state's budget this year, and staff members are asking the legislature for almost twice what they had gotten before. The program covers children from birth to 18 years of age, and is funded by the VFC program, 317, and general revenue funds. They are considering a minor amount of funding for some adult vaccines for a one year period. They are considering Hepatitis A and B for at risk populations, correction facilities, and the health department; however, this is very tentative and would only be for a limited time period.

The Idaho Department of Health & Welfare purchases vaccines through the VFC program and administers and oversees the program. Idaho establishes memoranda of understanding with providers and conducts annual site visits to ensure vaccines are stored and administered correctly. Due to the cost of the vaccines, Idaho has had to create a limited selection process for providers whereby all of the recommended vaccines are available, but a committee oversees the selection of which manufacturers are included. As they now use McKesson for distribution (with the provider orders going directly to McKesson), they are able to expand the choices (brands) with no additional cost.

Idaho does have an immunization registry called IRIS (Immunization Reminder Information System), but it's not mandatory for providers to register each vaccination. About 90 percent of providers participate. The system is designed for children, but opened for any one who is interested. Originally, this was a controversial legislative decision as it didn't have strong buy-in because of physicians' concerns about the data entry time needed. In contrast, almost all (96 percent) parents do register their children. Idaho is an "opt-in" system where parents must enroll or authorize inclusion of their children in the registry.

Idaho's major challenge is the uncertainty of state funding. According to state officials, the Universal Vaccine Purchasing System's funding is determined by the legislature, and if they decide to reduce, not renew, or not purchase certain vaccines that could become a problem. When asked for advice to other states considering a Universal Vaccine Purchasing System, Idaho suggested tying the funding to the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention recommendations, so there is a link to the legislature and funding. This way, if the recommendations change, the state would have to fund the program. Additionally, this would not leave the system's future up to individuals who could decide not to cover the additional cost. As a program staff person said, "the expected would be increased vaccines, no guessing games, no surprise factor of if the program will get funded."

Maine

Begun in the 1990s, Maine's program covers all children from birth through 18 years, and provides some adult vaccination services. The program was universal, but recently became select because they didn't have enough state or 317 money to cover the new vaccine costs (Menactra, Hepatitis A, HPV, and Rotavirus). Program officials would like to return to being universal, and have gone back to state for funding.

The system is financed via federal funds (VFC and 317), state funds, and HMO reimbursements. The Universal Vaccine Purchasing System also receives voluntary contributions from HMOs (Johnson, 2000). The contributions are based on the proportion of covered children within the HMO. The contributions are used to purchase vaccines, and not used for operating expenses or administration fees. MCOs seem to be happy with the system as they appreciate the less expensive vaccine costs.

Vaccines are purchased from the CDC, and McKesson handles the distribution. The ordering system was developed by Wisconsin, and was then tailored by a private vendor for Maine. The program uses an interface between the immunization registry (VACMAN) and the registry. Maine's immunization registry, called ImmPact (Johnson, 2000), is a lifetime registry, and is designed for all populations, not just children. The registry is also a useful tool for providers for tracking immunization status and allowing for easy identification of children due or overdue for their immunizations. The system is also a useful tool for the state by providing information for quality improvement, and for analyzing immunization rates by region and local area to identify unprotected and at-risk populations.

Providers find the program convenient because they do not have to separate their vaccine supplies (i.e., one for the federal vaccines and one for those purchased privately). However, some providers don't want to take the state vaccines for the VFC (which is a barrier to low income) because the CDC requires that underinsured patients go to the Federal Qualified Health Centers (FQHCs) who don't want them unless they become full-patients and private providers don't want to lose patients.

In terms of advice for other states, state officials said "it's all a money issue." They do recommend an electronic registry system.

Massachusetts

While Massachusetts had provided universal vaccines for children since the colonial period, they recently moved to a select status because of the cost of the newer vaccines. Currently, they do not provide HPV, but did receive money to begin providing Menactra and Rotavirus vaccines. While primarily covering children, Massachusetts' Universal Vaccine Purchasing System does include some vaccines for adults. They also manufacture their own DPT vaccines. For adults, they provide approximately half a million doses of TD and influenza vaccine. They also offer pneumococcal polysaccharide immunizations and Hepatitis A and B vaccines at some specific sites (e.g., Hepatitis A in public health sites and Hepatitis B only for public safety workers and college students).

The State purchases its vaccines through the VFC program and recently switched their distribution system to McKesson as a requirement from the CDC. Vaccine orders continue to come to the central office, via fax and email, and are then entered and ordered. Massachusetts is still working on getting a registry, and is not sure if it will be a mandatory or voluntary system. Although the CDC encouraged the direct distribution system, Massachusetts does not expect to save money because the current system is already so localized (140 programs across the state), there is little over-night shipping costs as all are locally picked up.

According to program officials, physicians like the program as they do not bear any risk for purchasing vaccines and, under this new distribution system, they will continue to support the program as the state would continue bearing the financial risk. In addition, physicians are able to charge administration fees which may be reimbursed by private insurance or Medicaid.

While this program has had tremendous support from the Massachusetts Legislature, the program faces shortfalls due to the disjunction between when the new state budgets are developed and approved and the time when the CDC bases its prices for the year and the additions to the recommended vaccine schedule.

One program official's advice for Maryland was "Get lots of money, it's very expensive".

Michigan

Michigan does not have a universal program because it has an agreement with FQHCs that allow the local health departments to vaccinate. The state funds all non-VFC kids for Hepatitis B and the vaccinations are done at birth in the hospital. In all, Michigan has 1600 VFC providers with 4000 physicians participating in the program. Although they do not have a universal purchasing system, they can provide some interesting lessons for Maryland. They do have a comprehensive registry system that covers birth to death. Providers are required to submit within 72 hrs of vaccination. Using an on-line website, they are able to transfer billing data or enter in the system. Starting in January 2008, they will also be able to utilize an on-line inventory reporting system.

Some HMOs provide reimbursements for children who are up-to-date on their immunizations as an extra incentive for providers. While the state does not do this, providers may look at their numbers in the website.

Currently for the VFC vaccines, there is a central depot in Lansing that provides the vaccines to each local health department (84) who then sends them to the providers. This, however, will change in January when they will convert to a central distribution system using McKesson to provide vaccines directly to provider offices. This change was required by CDC. In terms of recommendations for Maryland, Michigan officials said that a "Registry is the key, [it can be] used it in many ways."

Nevada

Like other states, Nevada moved from "Universal Purchase" status to "Universal Select" status when Prevnar came out. They have not added any of the newer vaccines to the list of vaccines it universally provides. The Nevada legislature no longer funds the purchase of some of the vaccines it had purchased before. It moved those funds into its S-CHIP match. Vaccines are purchased through 317 money. Administrators of Nevada's VFC program attempted to move to "VFC only" status a few years ago but met opposition from the Health Plans in the state. Those plans do not now have to pay for vaccines they would have to pay for in a non-universal purchase environment.

Nevada's status as an underfunded "Universal Select" state creates confusion in the providers' offices that often send patients to other places to receive the vaccines that are not publicly provided. Many of them do not keep stocks bought with private money.

New Hampshire

New Hampshire has had a universal vaccine program for children only but has considered offering adult vaccines (but no funding is available). They were considered a Universal Vaccine Purchasing state until recently when the increase in the new vaccines stressed the system, but the insurers are still supportive. The New Hampshire Universal Vaccine Purchasing System uses VFC program and 317 grant funds for children who qualify for these programs and state funds are used to cover the remaining population.

Each insurance company contributes funds to a designated account based on the proportion of covered lives they have in the state (extrapolated from the number of children in the state). The state calculates the amount, the insurance companies get a review period, and then they negotiate. To assist in the process, New Hampshire has a Vaccine Association Board that includes the three largest insurance companies, DHHS, and pediatricians.

By having a universal select system, program officials feel that they can concentrate on monitoring the usage and ensuring that doctors always have unexpired vaccine by reallocating unused vaccines. Additionally, officials say they are not spending time "policing the doctors and

making sure they separate the VFC vaccines or on marketing.” Doctors appreciate the system because it is easy and minimizes their financial risk.

While this program is successful, according to a report issued by the Center for State Health Policy (Howell-White & Scotto Rosato, 2006) the administration fees charged by physicians present a challenge to the program’s vaccine coverage rate. Reporting on a survey of physicians, New Hampshire found that vaccinations were often only provided as part of a well-visit which ranged from \$70-\$250; thus, these costs could present a real barrier to vaccination coverage.

In January the state distribution system will be through McKesson. For the ordering system, the providers will still go through the state that will then order through the CDC and then it will be sent to McKesson. Extra vaccines such as the flu have been purchased from the Minnesota Multistate Program.

New Hampshire officials report not having a registry system, and no plans to create one. They do have concerns that as providers move to electronic records they won’t voluntarily participate in a registry.

While New Hampshire offers some good suggestions for a system, they are a largely private practice state, with only 30 percent Medicaid eligible, with most people going to private practitioners, only two health departments (one that is almost never used), and where Federally Qualified Health Centers are mostly private clinics. Recommendations for Maryland were to “make sure your funding is in place, you know what you are getting from CDC and it won’t be enough, and you need it from other funders, we require all providers to be VFC.”

North Carolina

North Carolina has had a Universal Select Vaccine purchasing system for seven years. The program is mostly for children, but has some very limited services for adults (tetanus boosters, MMR for college students, and Hepatitis A and B for those at risk for STDs). The select status was forced by funding issues when they were unable to supply all the vaccines for non-VFC children (e.g., Prevnar). They are still in the process of getting back to their universal status.

The state general assembly is considering a fund that the insurance companies would pay into, and then the funds would be used by the state to purchase through their federal contract. State officials report that it wasn’t hard to convince insurance companies that this would save them money; however, the CDC “didn’t like” this. The CDC’s concern was that it would damage their leverage over price with the manufacturers. While some vaccine manufacturers supported the program and some did not, it has not passed the assembly and North Carolina is currently doing a pilot program.

Currently, the distribution system is handled by a Virginia-based company, but they will be switching to McKesson. The ordering system entails the physicians sending, calling or faxing their order to the state. Only about one-third of physicians (30-40 percent) use the immunization registry system (VACMAN) to order their vaccine supplies.

North Carolina's immunization registry is voluntary, but they are considering making it mandatory. The concern over this is the costs it will impose on the providers. The state official reported that physicians in North Carolina are concerned that a registry takes nursing time away from patients, and there is also concern that some providers are not "tech savvy".

Rhode Island

Rhode Island has had a universal vaccine program for children for over 25 years. The state funds their program from the VFC program, 317, and state funds. The state also collects funds from insurance companies. Although the CDC discourages private funds being used to purchase VFC vaccines, the state's program funding system preceded these rules and, therefore, their methods have been "grandfathered in" to allow the private funds to purchase vaccines through the VFC program. Approximately 0.45 percent of each insurance premium goes for the vaccine program into a restricted receipts account.

Physicians get the vaccines directly from the state department of health; however this is changing as CDC is requesting that states move to a direct distribution system. Rhode Island also has an "electronic, integrated child health information system (KIDSNET)" that allows providers to track a child's immunization history as well as providing valuable data to support the state's outreach and education efforts (Healthy Rhode Islanders Progress Review, 2000; www.ri.gov).

Currently the program is restricted to childhood vaccines, but according to program officials the state's Legislature is close to passing a law to purchase influenza and pneumococcal vaccines for adults. The state does have a few programs for adults. For instance, it uses some of its 317 grant money to purchase Hepatitis B vaccine for women prisoners.

Vermont

Vermont is listed as a universal state by the CDC. But recently they have had to apply restrictions due to the expense of funding on HPV and Menactra vaccines. HPV is covered for 11 and 12 year old girls (soon to cover 15 year olds), and Menactra for college students living in a dorm. Funding is a major issue here as it is in other states. Vermont is currently working with their banking and insurance department on how to get the insurance industry to voluntarily contribute to the program on an aggregate, or client basis. In this way, providers would contribute to a purchasing pool. Ideally, the VFC would pay for the VFC eligible children, 317 for uninsured, and the providers would fund the others. Although the children's immunization rates are considered good, Vermont is up-dating the school vaccination requirements and introducing a bill to write rules for daycare.

Vermont officials report that they keep the program going with providers by doing a lot of provider education, doing mailings, and by using their website, and through face-to-face contact with providers.

Vermont's Mandatory Registry program is different than the distribution system that keeps track of the vaccines. Additionally, the registry system is not robust enough to do vaccine coverage estimates, so the state must rely on chart review. Moreover, no one knows what the coverage rates for adults are although Vermont is piloting some adult vaccination programs.

The distribution system entails the vaccines being moved from the central office to district offices and then to the provider offices (170). The distribution system keeps track of redistributing the vaccines, and provides for frequent face-to-face with providers which allows the state to up-date and educate them. This system is beneficial for Vermont, because they have a small population but a large distribution region. The drawbacks to utilizing this type of system are the intensiveness in terms of work and resource--- packing, storing, and distribution are labor intensive.

The total budget for 2007 was \$10 million for vaccine purchase (863 per boy, 1100 per girl) with \$2 million in operation and distribution costs.

An official from Vermont also pointed out one special challenge. With universal purchase some providers lose the office habit of ordering themselves and when some new vaccine requires them to do so they are not adept at doing it.

In terms of advice for Maryland, one program said "Go in with your eyes wide open, it's not easy, [and] difficult to keep up with the new universal vaccines."

Washington

Washington State has been a Universal Purchase state since 1989. The state official with whom we spoke thought the system worked very well; however, there were challenges that were mentioned.

Finding the money to continue being a universal purchase state with the newer, more expensive vaccines has required the vaccine office there to develop strong relationships with the financial officers responsible to the Governor and with the financial officers responsible to the legislature. Those officers must stay up-to-date with a very complex system that requires additional funding whenever the ACIP recommendations are updated.

Every change provides a challenge. Different providers handle the changes differently. Some wait for the state to provide funding before acting on the new recommendations. The state's practice is that the recommendations are not official until they are published in the CDC publication *Morbidity and Mortality Weekly Report*. This allows the state officials some lead time to get their part-time legislature to move on the funding issues. In the meantime some providers are using private sources to obtain vaccine and some are not.

The budgeting can be complicated. The uptake of all adolescent vaccines, especially the HPV vaccine is hard to predict. Many adolescents do not visit a health care provider every year. The

vaccine office meets with the governor's budget people on a quarterly basis to keep "on top of" these difficult budget problems.

Washington is "grandfathered in" to the CDC contract and is thus allowed to buy all its supply of vaccine at "public prices."

Washington will soon be moving to integrate a module that will allow vaccine ordering, and then inventory control can be integrated into its strong Immunization Information System. The official from Washington said that this would be "really helpful, but it doesn't have to come first."

The Washington official reported that a disadvantage of being a Universal Purchase state is that the Federal 317 funds are dedicated solely to childhood vaccines, while other, non-Universal Purchase states may use some of those funds for adult initiatives.

Wisconsin

Wisconsin has considered a Universal Vaccine Purchasing System program, but doesn't have the state funding to implement it, so they haven't had a major initiative in their state. They do receive 317 and VFC funds, and self-distribute to all registered providers.

They have built a registry with public funds made available through shareware and used by about 12 other states, though the state does not modify or support the software; that is done locally. This state is of interest however, as they have a voluntary, web-based registry. They are still working to bring providers on board, and are getting a lot of positive feedback. The registry system allows them to estimate vaccination coverage. With the only other data being the National Health Immunization Survey, they ask their local offices to use the registry data to do population based estimates, thus they are able to provide accurate assessments for care givers.

Wyoming

Wyoming implemented a select universal purchasing system in September 2007. Its unique circumstances lead to that decision.

Wyoming had run a relatively large surplus because of the increase in energy prices for many years. At the same time it had difficulty with its immunization rates because the widely dispersed population made the state relatively unattractive for HMOs and other health organizations. Health care access in the state was "problematic" and this was a real impediment to immunizations. A high proportion of the state's children were VFC eligible. When their VFC program was found "not in compliance" during a review, they decided to implement another strategy.

Though it may soon be universal, we have classified Wyoming as universal select because purchase of Rotavirus and HPV vaccines has not yet been implemented. Since the new system

has been in operation for only a year, they do not have statistics to show its success. But they are optimistic. They estimate the cost of the program will be \$3.5 million next year.

Their lessons for any state considering the introduction of universal vaccine purchasing:

- First, the state will need extra staff
- Second, the state must plan ahead to allow the CDC to add the new amounts of vaccine to the contract.
- Third, the state must plan carefully so that existing provider inventories will be accounted for, and the plan should allow the providers to be compensated for those inventories in some way.

Table 9

State Purchasing Status in "Universal Select States" of the Most Expensive Vaccines					
State	Type of Purchase System (as classified by the CDC in 2006)	Does the state provide financing of recommended HPV vaccines (Gardasil)?	Does the state provide financing of recommended PCV vaccines (Prevnar)?	Does the state provide financing of recommended MCV4 vaccines (Menactra)?	Does the state provide financing of recommended Rotavirus vaccines (Rotateq)?
Connecticut	Universal Select	No	No	No	No
Hawaii	Universal Select	No	No	No	No
Idaho*	Universal Select	No	Yes	Yes	Yes
Maine	Universal Select	No	No	No	No
Massachusetts**	Universal Select	No	Yes	Yes	Yes
Nevada	Universal Select	No	No	No	No
North Carolina	Universal Select	No	No	No	No
North Dakota***	Universal Select	No	Yes	Yes	Yes
South Dakota	Universal Select	Yes	Yes	No	No
Wyoming	Universal Select	No	Yes	Yes	No
Alaska	Universal	Yes	Yes	Yes	Yes
New Hampshire	Universal	Yes	Yes	Yes	Yes
New Mexico	Universal	Yes	Yes	Yes	Yes
Rhode Island	Universal	Yes	Yes	Yes	Yes
Vermont	Universal	Yes	Yes	Yes	Yes
Washington	Universal	Yes	Yes	Yes	Yes

* In January 2008 the legislature will consider whether to fund HPV vaccines.

** As of July 2007 Massachusetts began to cover rotavirus and meningitis vaccines

*** As of January 2008 North Dakota will become a "VFC only" state.

1.1 Summary of Findings from Interviews with Officials from Other States

Most states with a Universal Vaccine Purchasing System limit their program to children. Most have three funding sources for the program (the VFC program, the federal Section 317 grant, and state funding), and purchase their vaccines from the CDC through the VFC program. A few of the states receive funds from private insurance companies to cover the proportion of children that would normally be reimbursed by insurance companies/HMOs. Some states have "grandfathered in" systems that required insurance companies to fund vaccines, while others are trying to develop special designated funds through which insurance companies can contribute.

In general, state officials report that providers are very supportive of Universal Vaccine Purchasing System systems. When health care providers did voice concerns, they usually resulted from the states' vaccine registries that were difficult or time-consuming to use. However, these systems are critical since they can be connected to ordering systems.

Most states also have a vaccine registry system. The systems vary a great deal in terms of their registry system's connection to the ordering system, whether they are mandatory or voluntary and whether they are for children only.

It was found that the challenges for a universal purchase system include:

- That it is perceived to be very expensive
- That future increases in both vaccine costs and the number of recommended vaccines are expected to elevate the cost of a Universal Vaccine Purchasing System over time.
- That decreased Section 317 grants and other public funding sources shifts the cost of a Universal Vaccine Purchasing System over time to other sources such as the State; that using private funds might necessitate purchasing non-VFC vaccines further increasing costs.
- That a strong immunization information system and a strong ordering and distribution system should be in place to accommodate universal purchase.
- That if such a system is adopted it should include funding mechanisms that allow the state to quickly adopt new vaccines.
- That a universal purchase system requires even quicker and more accurate estimates of the upcoming costs. Disruptions in the system occur when new vaccines are recommended and the state cannot respond quickly to the new needs of providers.

1.2 Regression Analysis

Our regression analyses of the National Immunization Survey data showed no improvement in immunization rates associated with universal purchase states when compared with states, like

Maryland, with “VFC enhanced” systems. Not only were the differences not statistically significant, but on critical vaccine coverage measures the VFC enhanced states were found to have outperformed the universal purchase states. For example, VFC enhanced states averaged a 77.18 percent coverage rate while the universal purchase states averaged 74.5 percent on the most comprehensive measure for children 19 to 36 months—4 DTP, 3 polio, 1 MMR, 3 Hib, 3 HepB, and 1 varicella.

A more detailed explanation of these results is presented in Appendix H.

1.3 Cost Estimates

When the governor of Massachusetts proposed this year that the state return to Universal Purchase status (including the purchase of HPV vaccine), the governor indicated that the total cost to the state would be about \$61.5 million.⁵¹ Massachusetts is “grandfathered into” the CDC contract. Adjusting for the difference in the populations of the respective states (Massachusetts has about 10 percent more people than does Maryland), we could extrapolate that Maryland’s cost under the CDC contract would be about \$54 million.

Table 10 provides a summary of potential costs for a universal vaccine purchase system. It compares the per dosage and total costs for three options for universal vaccine purchase 1) purchase through the CDC, 2) purchase on the private market and 3) purchase through a purchasing alliance. We calculated the cost of universal vaccine purchase for Maryland children using three sources of vaccine—the CDC, the private-sector “retail” price, and a purchasing alliance. The estimates based on the CDC contract price are more precise than the other two estimates. Detailed descriptions of the calculation method for each option and evaluation of each possibility are as follows:

- **Number of Doses:** Our estimates were developed by taking the current vaccines that the state purchases through the CDC contract and extrapolating from the doses for each vaccine purchased for public use to the number of additional doses that would need to be purchased to cover those vaccines now purchased by others. Since the percentage of children whose vaccines are purchased with public funds decreases as the children get older, the percentage of children served by the public sector in each of four age ranges was calculated. The approximate ages of the children when they are likely to receive a particular vaccine was then estimated. This allowed the calculation of an estimate of the percentage of children served by the private sector for each vaccine. The number of doses needed in the next 12 months was then calculated.
- **CDC Contract Price:** We estimate that it would cost Maryland about \$55.5 million each year to purchase vaccines for all children through the CDC contract prices (posted as of September 18, 2007).⁵² Currently Maryland purchases VFC vaccines through this contract. It is, however, likely that the CDC would not allow Maryland to purchase vaccines for non-VFC children through this mechanism. Moreover, it is widely believed that such purchases would erode the difference between the private and public prices of

the vaccines (and therefore not save money in the long run) or that it would undermine the ability of the market to direct new funds into vaccine research and development.

- **Private-sector Price:** We calculated that it would cost Maryland more than \$74 million if all childhood vaccines were purchased through the private sector. The pricing is based on a 2007 list posted on the same CDC web site (above) and does not reflect any possible negotiation for a lower price.
- **Purchasing Alliance Price:** The third estimate falls between the other two estimates. Purchasing alliances such as MMCAP say that they save about 23 percent off the Average Wholesale Price. Using that as a guide, a price was estimated between the CDC price and the private sector price. Our estimate of nearly 63.4 million dollars does not include administration costs. Our conversations with other states leads us to believe that the vaccine administration office would have to be increased at least 50 percent to accommodate the new tasks they would be required to perform. That would add approximately 150,000 dollars to the total cost.

**Table
10**

Twelve Month Estimate of the Cost of a Universal Vaccine Purchase System in Maryland in 2008								
Vaccine	Brand Name	Estimated number of doses distributed in the private sector	Dose price with the CDC contract	Estimated cost of vaccine with private sector extension of CDC contract	Dose price in the private sector	Estimated private cost of vaccine without negotiating a better price	Estimated Dose price with a Purchasing Alliance	Estimated cost of vaccine with a Purchasing Alliance
DTaP	Infanrix	25,661	\$13.25	\$340,011	\$20.96	\$537,857	\$16.14	\$414,150
DTaP-Hib	TriHIBit	12,983	\$25.91	\$336,390	\$42.89	\$556,836	\$33.03	\$428,764
DTaP	Tripedia	3,880	\$12.65	\$49,081	\$21.40	\$83,030	\$16.48	\$63,933
DTaP-IPV-Hepatitis B	Pediarix	52,641	\$47.25	\$2,487,263	\$70.72	\$3,722,740	\$54.45	\$2,866,510
DTaP	DAPTACEL	26,548	\$13.25	\$351,761	\$22.04	\$585,115	\$16.97	\$450,539
Influenza	Fluzone	64,258	\$10.15	\$652,407	\$11.72	\$753,099	\$10.68	\$685,971
Influenza-Preservative Free Pediatric	Fluzone pediatric	81,099	\$12.77	\$1,035,632	\$14.26	\$1,156,469	\$13.27	\$1,075,911
Influenza (Live, Intranasal)	FluMist	39,606	\$17.65	\$699,049	\$17.95	\$710,931	\$17.75	\$703,010
Hepatitis A Pediatric	Havrix	58,340	\$12.25	\$714,659	\$28.74	\$1,676,687	\$22.13	\$1,291,049
Hepatitis A Pediatric	VAQTA	58,285	\$12.25	\$713,986	\$30.37	\$1,770,113	\$23.38	\$1,362,987
Hepatitis B-Hib	COMVAX	2,778	\$27.75	\$77,080	\$43.56	\$120,997	\$33.54	\$93,167
Hep B Preservative Free Pediatric	ENGRIX-B	18,927	\$9.10	\$172,236	\$21.37	\$404,465	\$16.45	\$311,438
Hep B Preservative Free Pediatric	RECOMBIVAX HB	16,000	\$9.50	\$151,998	\$23.20	\$371,193	\$17.86	\$285,818
Hib	ActHIB	44,818	\$8.28	\$371,095	\$21.78	\$976,139	\$16.77	\$751,627
Hib	PedvaxHIB	35,409	\$10.83	\$383,476	\$22.77	\$806,258	\$17.53	\$620,818
Human Papillomavirus	Gardasil	158,531	\$96.75	\$15,337,932	\$120.50	\$19,103,036	\$104.67	\$16,592,967
Meningococcal Conjugate	Menactra	126,404	\$73.09	\$9,238,862	\$89.43	\$11,304,341	\$78.54	\$9,927,355
Measles, Mumps, and Rubella	MMRII	71,020	\$17.60	\$1,249,965	\$44.84	\$3,184,556	\$34.53	\$2,452,108
Pneumococcal conjugate	Prevnar	105,895	\$62.14	\$6,580,311	\$79.19	\$8,385,834	\$67.82	\$7,182,152
Polio	I POL	45,192	\$11.06	\$499,824	\$22.80	\$1,030,374	\$17.56	\$793,388
Rotavirus, Live, Oral, Pentavalent	RotaTeq	68,257	\$55.05	\$3,757,528	\$66.94	\$4,569,090	\$59.01	\$4,028,048
Td Reduced Diphtheria Toxoid & Acellular Pertussis	ADACEL	56,818	\$31.75	\$1,803,951	\$37.43	\$2,126,685	\$33.64	\$1,911,529
Td Reduced Diphtheria Toxoid & Acellular Pertussis	BOOXTRIX	41,005	\$30.75	\$1,260,899	\$36.25	\$1,486,426	\$32.58	\$1,336,074
Td	DECAVAC	4,841	\$17.38	\$84,135	\$19.14	\$92,655	\$17.97	\$86,975
Varcella	Varivax	119,153	\$59.15	\$7,047,874	\$74.56	\$8,884,040	\$64.29	\$7,659,929
	Grand Totals:	1,338,347		\$55,397,404		\$74,398,967		\$63,376,219

The total estimate of the cost to the state to implement a universal vaccine purchase system for children's vaccines is \$63,376,000 plus \$150,000 or \$63,526,000.

But it must be remembered this is based on an assumption that immunization rates will not increase above the rate already found in children whose vaccine is provided free through the VFC program and that there will not be a large increase in the demand for HPV vaccine.

1.4 Potential Costs

The state must also be prepared for an increase in the use of vaccines that might accompany the introduction of a new program. The introduction of such a program should be accompanied by the fiscal flexibility that would allow for higher immunization rates. Table 10 can be adjusted to

create estimates of how high these possible costs might be. In Table 11 the number of doses estimated in the private sector has been adjusted. Instead of assuming the same immunization rates as VFC children, the number of doses needed to make the immunization rate approximately 100 percent is estimated. For HPV vaccine, it is assumed that every girl between 11 and 18 who had not already been immunized would receive all three doses in the next fiscal year period.

These assumptions are not likely to occur, but they give an estimate of the maximum amount that the state may have to pay to purchase these vaccines for all children in Maryland.

The important difference between Table 10 and Table 11 is in the estimate of the cost of HPV vaccine. By assuming all the young girls between 13 and 18 would use the opportunity to make their immunization current Table 11 projects that the cost of providing such a vaccine has the potential to increase about another 25 million dollars. Together with a potential increase of about \$500,000 in the other vaccines, this would bring the potential cost of such a program to about \$90,050,000 (\$88,900,000 + \$150,000 in increased administrative costs). Of course, it is not clear that the prices will remain stable or that Maryland will be able to negotiate a price for each vaccine as low as the estimate of the price they may be able to negotiate.

See Appendix F for a step-by-step explanation of the method used in calculating these numbers.

Table 11

Estimate of the potential cost of a universal vaccine purchasing system in Maryland for the first 12 months of the system								
Vaccine	Brand Name	Potential number of doses distributed in the private sector	Dose price with the CDC contract	Potential cost of vaccine with private sector extension of CDC contract	Dose price in the private sector	Estimated potential private cost of vaccine without negotiating a better price	Estimated Potential Dose price with a Purchasing Alliance	Estimated Potential cost of vaccine with a Purchasing Alliance
DTaP	Infanrix	27,012	\$13.25	\$357,907	\$20.96	\$566,166	\$16.14	\$435,947
DTaP-Hib	TnHIBit	13,666	\$25.91	\$354,095	\$42.89	\$586,143	\$33.03	\$451,330
DTaP	Tnpedia	4,084	\$12.65	\$51,664	\$21.40	\$87,400	\$16.48	\$67,298
DTaP-IPV-Hepatitis B	Pediarix	55,411	\$47.25	\$2,618,171	\$70.72	\$3,918,674	\$54.45	\$3,017,379
DTaP	DAPTACEL	27,945	\$13.25	\$370,274	\$22.04	\$615,911	\$16.97	\$474,251
Influenza	Fluzone	67,640	\$10.15	\$686,745	\$11.72	\$792,735	\$10.68	\$722,075
Influenza-Preservative Free Pediatric	Fluzone pediatric	85,367	\$12.77	\$1,090,139	\$14.26	\$1,217,336	\$13.27	\$1,132,538
Influenza (Live, Intranasal)	FluMist	41,691	\$17.65	\$735,841	\$17.95	\$748,348	\$17.75	\$740,010
Hepatitis A Pediatric	Havrix	61,410	\$12.25	\$752,272	\$28.74	\$1,764,934	\$22.13	\$1,358,999
Hepatitis A Pediatric	VAQTA	61,353	\$12.25	\$751,564	\$30.37	\$1,863,277	\$23.38	\$1,434,724
Hepatitis B-Hib	COMVAX	2,924	\$27.75	\$81,137	\$43.56	\$127,365	\$33.54	\$98,071
Hep B Preservative Free Pediatric	ENGRIX-B	19,923	\$9.10	\$181,301	\$21.37	\$425,752	\$16.45	\$327,829
Hep B Preservative Free Pediatric	RECOMBIVAX HB	16,842	\$9.50	\$159,998	\$23.20	\$390,729	\$17.86	\$300,861
Hib	ActHIB	47,177	\$8.28	\$390,626	\$21.78	\$1,027,515	\$16.77	\$791,186
Hib	PedvaxHIB	37,272	\$10.83	\$403,659	\$22.77	\$848,692	\$17.53	\$653,493
Human Papillomavirus	Gardasil	396,548	\$96.75	\$38,366,088	\$120.50	\$47,784,064	\$104.67	\$41,505,413
Meningococcal Conjugate	Menactra	126,407	\$73.09	\$9,239,036	\$89.43	\$11,304,555	\$78.54	\$9,927,543
Measles, Mumps, and Rubella	MMRII	71,020	\$17.60	\$1,249,965	\$44.84	\$3,184,556	\$34.53	\$2,452,108
Pneumococcal conjugate	Prevnar	105,895	\$62.14	\$6,580,311	\$79.19	\$8,385,834	\$67.82	\$7,182,152
Polio	IPOLE	45,192	\$11.06	\$499,824	\$22.80	\$1,030,374	\$17.56	\$793,388
Rotavirus, Live, Oral, Pentavalent	RotaTeq	68,257	\$55.05	\$3,757,528	\$66.94	\$4,569,090	\$59.01	\$4,028,048
Td Reduced Diphtheria Toxoid & Acellular Pertussis	ADACEL	56,819	\$31.75	\$1,803,985	\$37.43	\$2,126,725	\$33.64	\$1,911,565
Td Reduced Diphtheria Toxoid & Acellular Pertussis	BOOXTRIX	41,006	\$30.75	\$1,260,922	\$36.25	\$1,486,454	\$32.58	\$1,336,100
Td	DECAVAC	4,841	\$17.38	\$84,136	\$19.14	\$92,657	\$17.97	\$86,977
Varicella	Varivax	119,153	\$59.15	\$7,047,874	\$74.56	\$8,884,040	\$64.29	\$7,659,929
	Grand Totals:	1,604,854		\$78,875,063		\$103,829,328		\$88,889,216

1.5 Financing Alternatives

Even many advocates of universal purchase realize that, in the current environment, capturing the money that health plans now spend for vaccine acquisition would seem to be a prerequisite for Maryland's adopting a universal purchase system.

It is possible that funding mechanisms that apply funds currently being expended by health insurance plans toward universal purchase could be developed so they would avoid conflicts with ERISA. If drafted carefully, these mechanisms would likely be considered by the courts to be regulation of insurance and not regulation of insurers. New Hampshire has had such a system since before the VFC program was instituted. North Carolina considered such a law in the past year, but it was strongly resisted by some manufacturers. One vaccine manufacturer, however, did not object to such a system because it included a provision that allowed providers to choose between vaccines and thus preserved some competition.⁵³ Wyoming's new universal system was not strongly resisted because it is so small, but primarily because it was funded completely by public funds that were not diverted from private health insurance plans.

It is likely that alternative finance systems will be resisted in Maryland if they use money from privately financed insurance systems to buy at prices at which publicly financed vaccines are sold. The resistance is due to the belief that buying for formerly private financed patients at the public financed price will cut company profits, unless they continue to close the gap between the public funds price and the private funds price.

There is evidence that since the beginnings of the VFC program the gap between private and public prices has closed; the CDC is concerned about this potential problem. Lance Rodewald, Director of the Immunization Services Division of the CDC told the *Concord Monitor*, "It's [using private funds to purchase vaccines at the CDC discounted price] a model we tend to discourage. . . We're just worried that if this is something that becomes a trend - that pretty much everybody's vaccine is bought through the discounted price - then the discount will evaporate completely."⁵⁴

Expressions of such concern were found in the literature and were expressed in the interviews and we found no adequate basis on which to refute these concerns. For example, the Institute of Medicine's Report on Financing Vaccines in the 21st Century found that:

Current government strategies for purchasing and assuring access to the recommended vaccines have not addressed the relationships between the financing of vaccine purchases and the stability of the U. S. vaccine supply. Financial incentives are necessary to protect the existing supply of vaccine products as well as to encourage the development of new vaccine products.⁵⁵

A 2006 article in the journal *Clinical Infectious Diseases* put the problem this way:

The United States has lost domestic vaccine production capacity. New capital is available only for products that provide an appropriate return on investment. Vaccines are complex to develop and manufacture, and new products will be developed only if there is anticipated profit. Adequate compensation for those who administer vaccines should be used as an incentive to champion immunization of appropriate patients.⁵⁶

We asked some states who were investigating reverting to a Universal Purchase System if they knew the current status of the CDC's position on this issue. One state representative replied that the CDC discusses this issue but they have found "nothing in writing" articulating CDC's position.

We did find something in recent publications from the CDC. In the "frequently asked questions" section of the User's Guide for Vaccine Contracts, published by the National Center for Immunization and Respiratory Diseases at the Center for Disease Control and Prevention (dated July 2006), we found this exchange:

Can states pool insurance funding and purchase vaccines through CDC's contracts for children not eligible for the VFC program?

The CDC vaccine contracts should not be used to purchase vaccines using private funds. This applies to all states, except those who were allowed to continue this practice at the beginning of the VFC Program. CDC believes that pooling of private funds to purchase vaccines could jeopardize the ability of CDC to obtain reduced price contracts. Federal vaccine contracts negotiated by the CDC provide substantial price discounts below the commercial prices available in the private market. Vaccine manufacturers participate voluntarily in this program. The system at present appears acceptable for the CDC to continue to receive price breaks. However, it is clear that to the extent there is a shift in the public/private shares through the establishment of private funding pools, such as a shift would likely have a significant impact on the potential for future public purchase at a discount.⁵⁷

Both because we have no argument which leads us to doubt the CDC's reasoning and because there appears to be a significant chance that the CDC would enforce this policy against a new state which tried to use the CDC contract using "private funds," we find that Maryland should not attempt to use this mechanism to lower purchasing costs.

2. Specific Findings Related to Immunization Information Systems (IIS)

We agree with the AAP's findings that continued improvements in the state Immunization Information system need to be encouraged; however, current funding of administrative fees is inadequate to cover the administrative costs associated with entering information into the state registry and other related, necessary record keeping activities. Improving the registry should include providing reimbursement to providers for this service.⁵⁸ As suggested in these AAP reports, an enhanced registry could provide many benefits to the State.

Requiring registry reports on the current immunizations received by all Maryland children would have a significant public health impact through allowing public health officials to identify specific geographical areas or providers with low vaccine coverage and intervene quickly to elevate coverage rates and prevent a disease outbreak in the local community. The NIS sample size for Maryland is sufficient to estimate coverage in Baltimore City, separate from coverage in the rest of Maryland. But the sample size is too small to estimate, with any precision, coverage rates in smaller geographical areas. Conducting surveys to estimate coverage in a locale is extremely time consuming and may underestimate coverage if not all provider records can be located. A comprehensive registry would provide these data, both improving vaccination rates and lowering the costs for ongoing research.

Ensuring that providers have easy access to the state registry could also reduce the incidence of children experiencing avoidable repeat vaccinations and the attendant physician office administrative costs. Providers would be able to use the registry to determine which vaccines a

new patient has had if a child changes physicians within the state. Without a reliable vaccine history, the provider may conservatively assume that the child has not been vaccinated and proceed to vaccinate, sometimes unnecessarily. Or the provider might delay needed vaccinations as he or she waits to receive records from the child's previous provider(s).

Providers could also use the registry to project future vaccine needs based on the previous year's information.

A comprehensive registry could also reduce record keeping for both school systems and physicians' offices by allowing electronic verification of vaccinations for school admissions. Vaccine information needed for school entrance or day care could be obtained easily from the registry. For example, school nurses or administrative staff could be authorized to electronically access the information, eliminating the costly and time consuming steps involved with obtaining paper records, verifying the data, and entering it into school database systems. Day care staff or other organizations that require immunization information but may not be given access to the registry due to confidentiality reasons would likely still require paper records, but a provider's administrative staff could print a copy from the register. This would be financially beneficial to providers. The AAP estimates that it costs \$14.75 each time a chart is manually pulled to provide parents with the child's immunization records.

3. Specific Findings Related to "Per-Shot" Reimbursements

The 2007 AAP report states that while combination vaccines increases compliance, physicians lose between \$10 and \$20 of revenue by giving one shot as opposed to three.⁵⁹ This is true even though the purchase cost is approximately the same and it takes less time to administer a combination shot with multiple antigens (e.g., DTP) than single antigen shots. But, administering combination vaccines does not reduce the amount of time a provider spends counseling the parent, obtaining consent, and charting. One manufacturer noted that there is resistance to improved, less costly, combination vaccines because of this system of per shot reimbursement. Reimbursement fees should, as much as possible, be per antigen rather than per shot.

4. Specific Findings about Vaccine Financing Policies

All manufacturers interviewed indicated that they had policies that helped the providers finance their products. These systems varied by company and by vaccine but the maximum seemed to be 120 days to pay back after ordering.

Section 5: Recommendations

The research team was tasked with investigating the universal purchase option and other available options. The team has investigated other options that were suggested. Our criteria included whether or not the option would alleviate the stresses explained in the findings section above. We begin by presenting our findings about Universal Purchase and then move to the other options suggested to us that we would recommend and then we move to those options that we would not recommend.

Option 1: Universal Purchase

- **We recommend the state *not* adopt universal purchase in the immediate future.**

The number one reason for this recommendation is cost; however, there are infrastructure considerations that also support this recommendation. Including administration costs, we believe the total cost of such a program would be about \$63.5 million dollars annually for the next few years (see page 45 for details.) The outlook for years after that is quite uncertain. Prices of the newer vaccines, such as Gardasil®, may go down as vaccines that compete with those vaccines are brought to market. But new vaccines might be recommended that would require quickly adding to the vaccine budget or, alternatively, facing confusion and missed opportunities at the vaccine provider level.

While new mechanisms (like the one we recommend below) might allow those costs to continue to be paid by the private sector, the potential for unexpected costs would still be high, unless that mechanism were well established before it took on this difficult and, potentially costly, task.

Our interviews showed that many of the states that had been universal purchase states have moved away from that status. Their reasons were the increasing costs associated with newer vaccines under that status.

The second reason is the lack of supporting data for the superiority of such a universal purchasing system. Our data analysis showed no statistical significance on measures of rates of immunization between states with universal purchase status and other states. Regression analysis showed that, under conditions that prevailed in 2005 and 2006, we could expect no improvement in immunization rates if we moved to a universal purchase system. If the stresses on the system become greater that dynamic might change. We recommend more rigorous measurements of those rates through a strengthening of Maryland's immunization information system.

The third reason that we do not recommend a universal purchasing system is the current uncertainty about the future direction of related national policies and uncertainty about the extent of the current stresses on the system. If there is a significant change in national policy, Maryland's expenditure of funds to prepare for a transition to Universal Purchase, and perhaps some of the money spent on vaccine purchase might not have been well spent. Studies are now in the field or being planned that will specify more clearly the nature of the stresses.

Finally, we cannot recommend Universal Purchase at this time because less expensive, and less disruptive, measures that will alleviate some of the symptoms of stress on the system are available. We discuss some of those below.

Universal purchase does have the potential to address two of the challenges that were identified: 1) the stress on the children's vaccine providers, and 2) the inequitable distribution of flu vaccine. But it is likely that the challenge of stress on providers would not be completely addressed by this solution. Much of the stress appears to be inadequate compensation for administering immunizations, when these represent an important proportion of the time that pediatricians see patients. That stress could continue and might be increased over the years in a universal purchase system.

The challenge of inequitable flu vaccine distribution would also remain in a universal purchase system. The market is changing rapidly and the production of flu vaccine will continue for many years to be subject to sporadic disruptions. It is not clear that any system put in place now would be able to adequately plan for changes and disruptions that will occur.

Changing to completely publicly provided vaccines has additional risks since the distribution system for publicly provided vaccines would need to be strengthened. Any disruption or mistakes in that system would be more costly in a new single distribution system than in the current multiple channel system. Building such capacity should be done before a universal system is implemented. But before venturing on such a potentially costly solution, alternative solutions should be explored and better data should be gathered.

Option 2: Increasing Medicaid Administration Fees for Immunizations

- ***We do recommend an increase in these fees.***

Maryland providers who were surveyed and the AAP believe that compensation for vaccine administration is inadequate. The federal ceiling for such fees was set in 1994 at over \$15, yet Maryland still compensates at \$10 per shot. Some private insurers have recently increased administration fees in Maryland.⁶⁰ An increase in Medicaid reimbursement would be a message to other insurers as well.

The Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimate that 20 percent of Maryland's children are covered by Medicaid.⁶¹ That percentage is probably higher among the youngest children who get the most vaccines. Assuming it is 30 percent and using the same formulas used in computing the results in Table 10, we estimated that about 3 million pediatric vaccines will be administered next year; about 900,000 of those will be covered by Medicaid. An increase in of \$5 in administration fees will cost Medicaid about 4.5 million dollars. Part of the funding would come from federal dollars; nonetheless, the state's share of the cost will be significant. The compensation, however, will go directly to Maryland immunization providers who appear to be under stress.

If Maryland's Immunization Information System can be improved, we recommend only paying the increased increment (or some portion of it) for immunizations that are registered in the information system. This would help ensure that the registry is used by all of Maryland's vaccine providers.

If it is thought that this should be only partially implemented one alternative would be to provide compensation for different vaccines at different rates. In stakeholder interviews with stakeholders with long history in the field and with many and varied responsibilities, we heard that the "per shot" basis of compensation created incentives for providers to ignore more convenient multiple antigen vaccines. Such vaccines are likely to increase immunization rates. Yet a provider is penalized for using them because the provider will be receiving less in administrative compensation than would be provided if multiple single antigen vaccines had been administered. To the extent possible such counterproductive incentives should be decreased.

Option 3: Provide incentives for provider participation in the immunization information system

- ***We do recommend providing some incentives for participating in Maryland's IIS.***

Paying providers to register the vaccines that they provide would directly support this practice and would provide incentives for good practices that would save them money over a period of many years. Our survey showed that most respondents are very supportive of a registry, yet do not use it. It is likely this is because they understand the long term benefits of such a registry, but feel they cannot afford to dedicate present resource to obtain those remote benefits. Paying them to register their vaccines would help solve this dilemma.

For the reasons given above we believe that the payment should be by antigen registered and not "by shot." Using the estimate of 3,000,000 pediatric vaccines administered per year (described above) and multiplying each shot by the number of antigens that will be administered leads to the estimate of about \$4,650,000. Appendix G provides the details and the assumptions that led to this estimate.

If the state would reimburse a practice for registering each recently administered antigen at 50 cents per antigen (and if the program were to be completely successful) the possible cost to the state would be \$2,325,000 dollars per year.

This money would go to practices that are stressed and it would create an incentive that would ultimately help all involved. The health plan would end up saving money through fewer record retrievals, fewer unnecessary administration of vaccines when a child moves to a different practice and in ease of data collection. The state would develop an instrument that would monitor the important immunization rates especially in the future. The current method used by the National Immunization Survey is very imprecise and in the future will likely not be up to the task of such monitoring. It is based on random digit dialing of land-based telephone lines, a technology that may soon not be as widely used.

The potential uses of a strong registry during an emergency also lead us to make this recommendation. It is estimated that registries saved over \$3 million in vaccine and vaccine administration fees that would have otherwise been spent in the wake of Hurricane Katrina.⁶²

The 50 cent number was arrived at based on a study that estimated the automated data entry of one shot cost a practice 24 cents. The study estimated that manually entered data cost \$3.24 per shot to enter.⁶³ The 50 cents number would create incentives for practices to automate the procedure and, when automated, stress on the practices due to low administration fees would be ameliorated.

This recommendation would best be funded by an assessment paid by insurance plans. See the recommendation below for more details.

Some of the challenges that have been identified are challenges to the future health of the vaccination provider system. Better monitoring of the situation, by providing earlier warnings that these stresses are leading to problems among some groups or in some geographical areas, would allow the state to move more quickly to adopt other strategies.

If possible, these incentives should be provided on a "per antigen basis" not a "per shot" basis. The "per shot" basis that is used for Medicaid administration fees already provides an incentive for the provider to resist going to shots that combine antigens. That incentive should not be increased.

If successfully implemented for pediatric practices such a system could be extended to adult vaccines. There are significant advantages to requiring or promoting immunization registration for adult flu and pneumonia vaccinations. With the pneumonia vaccine this registry could prevent under or over vaccination. A registry would be a method to unite the fragmented flu vaccine delivery system. Since some individuals prefer to receive their flu vaccination at places other than their medical home, such as a retail store, a registry could provide a useful method to keep track of the overall immunization rates in the state. Many elderly persons visit multiple physicians and could receive multiple flu vaccinations if they are unable to recall receipt of a vaccination. A registry would eliminate over vaccination for flu and pneumonia vaccine.

Reminder/recall systems could include cards that could be sent yearly to those who have received vaccinations in the past; a registry would be useful in identifying locations with lower vaccination rates that could benefit from more intensive outreach. Providers could access the registry to confirm vaccination of patients when seen in the medical home to avoid missed opportunities for vaccination and over vaccination. Registries would also be excellent infrastructure to have developed in case of pandemic influenza or bio-terrorism.⁶⁴

The administration of the Information Immunization System should also be strengthened to handle its new responsibilities. The total costs involved in strengthening administration would be in personnel costs and could be done by hiring two or more additional administrators or

administrative aides. Such personnel costs are roughly estimated to be about \$200,000 by estimating how much the Schaefer Center would charge the state to accomplish the mission.

Option 4: Mandate that immunizations not be subject to co-payments

- **We do recommend such an action.**

Maryland already mandates that vaccines are not subject to deductibles. Some states mandate that vaccines not be subject to co-payments. Although it will be of limited effect because many of the Maryland's Health Plans will be exempt from the mandate under ERISA, we believe that such a provision is good policy.

Vaccines, in general, provide a benefit not only to those who receive the vaccine but to the general population. The best reason for to require co-payments is to have a patient not use an unnecessary amount of a product or service. This reason does not apply to vaccines. Eliminating co-payments is therefore recommended.

Option 5: Create a public reporting system that requires health plans to report the reimbursements that they have paid out to cover the costs of vaccine and administration of vaccines.

- **We do recommend such a reporting system.**

Such a system would require about \$25,000 a year for the state to monitor and post the average reimbursements. Since personnel costs would be the major component of this reporting system, this cost estimate was arrived at by calculating the price the Schaefer Center would charge the state to provide this service. There would also be a small cost to the Health Plans that would likely be passed on the consumer. The main reason for this recommendation is that it is thought that it would "level the playing field" in the negotiations between the small practice and the Health Plans and would allow monitoring so that Health Plans would have some incentive to move more quickly in updating reimbursements when costs change. The Immunization Information System could be used to publicly post this information in a place where those who had the most interest would also have access.

Option 6: Establish a system of annual assessments of insured lives to pay for immunization related expenses that benefit the general population.

- **We do recommend this option.**

In 2002 New Hampshire made its formerly voluntary system for health insurers mandatory. North Carolina's legislature, this year, has been considering a similar mandatory assessment. See the New Hampshire law and the North Carolina bill in Appendix D and Appendix E.

In those cases the reason for the assessment was to buy vaccine through the CDC. We do not recommend that. However the things we do recommend would also benefit the insurance plans in general. The costs we envision are relatively small but they will serve to take a burden away for the health insurance plans. We believe that the cost of registering an immunization should be considered a part of the administration of the vaccine, and we believe that registration will save

health plans money in the future. We therefore reason that they should provide at least a significant portion of the immediate costs.

Besides the approximate annual \$2,000,000 cost of the incentives and administration related to the Immunization Information System (described above), the assessment could examine other ways to strengthen and protect immunization delivery in Maryland and to prepare the state for possible future crisis related to vaccine-preventable infections.

Establishing such an assessment system will allow Maryland to move more quickly in any crisis or if stress on the system becomes greater.

Alternatively the state could take the needed money from general revenues. The benefits of these policies will accrue not only to all those insured, but to a slightly lesser degree to all Marylanders. The choice is a close one. But our research team has opted for the greater future flexibility that an assessment system would provide.

Option 7: Require Health workers (with opt out conditions) to be immunized for flu.

- ***We do recommend this option.***

Our stakeholder interviews informed us that there are substantial opportunities to improve the rates of vaccination of health workers – particularly against influenza. We recommend that they be required to sign a form opting out of a flu shot. The kind of form we have in mind can be found in Appendix E.

Option 8: Purchasing select children's vaccines for all children in Maryland

- ***We do not recommend purchasing select vaccines for children.***

There is some evidence that making, for example, an HPV vaccine available for free to the population would satisfy many who oppose such a vaccine being made mandatory for school attendance and those who believe the vaccine will prove very cost-effective.

The problem we have with recommending this course is that the precedent of picking and choosing particular vaccines for special treatment at the state level will require continuing expenditures of resources to decide the issues. These decisions are likely to be contentious both politically and morally. Maryland's system of funding children's vaccines for the underinsured that are recommended by the ACIP avoids these problems.

The controversy over a recent article in *JAMA* demonstrates one of these problems. Matthew Davis argues that the decisions by some states to fund some vaccines and not others, for example the decision by some states to move from universal to universal select systems represented a non-systematic prioritization of vaccines and that this prioritization should be made national and overt.⁶⁵ This prompted many in public health and pediatrics to "keeping the universal

recommendations whole is a critically important priority.”⁶⁶ It is not clear that there would be any value in Maryland’s getting involved in such disputes.

Option 9: Purchasing select vaccines for all adults in Maryland who are recommended to receive the vaccines

- **We do not recommend purchasing select vaccines for all adults in Maryland at this time.**

Two vaccines were specifically suggested for increased state purchase for adults: flu vaccine and HPV vaccine. The findings section details the background for our recommendations that these vaccines not be purchased by the state for adults at this time. Some of the reasons for this recommendation are vaccine specific but others have general applicability.

The current increase in supply of flu vaccine, the changing supply and distribution patterns, the current availability of flu vaccine at no or low cost to high risk groups, lead us to recommend that the state not make flu vaccine available to all recommended adults at this time.

Another suggestion for such a program was for the state to purchase vaccines that combat HPV infections. As reported in the Findings section, we could not recommend such a program for a variety of reasons.

The rarity of cervical cancer, the additional sources of HPV infection not covered by the existing approved vaccine nor in the most prominent vaccine now in clinical research, the unanswered questions regarding long-term safety and use of the approved vaccine, and the importance of vaccination prior to sexual debut, are among the findings that lead us not recommend universal purchase of HPV vaccines for adults at this time.

While HPV is a special case for these reasons, purchasing other adult vaccines is also not recommended for reasons other vaccines share with HPV vaccines.

There are logistical barriers to state purchase of vaccines for adults. It would take significant amounts of time and money to plan and to build an infrastructure to distribute vaccines to adults and to provide quality control. With children’s vaccines it is assumed that the provider system now used for the VFC program could be adapted and expanded to provide the infrastructure needed for a new program. This cannot be assumed for adult vaccines.

State action at this time might also preempt private market action. Merck sponsors a Vaccine Patient Assistance Program that helps provide vaccines produced by Merck (which includes vaccines for HPV, MMR, PPV23, hepatitis B, hepatitis A, varicella, and zoster) to some individuals 19 and older.

In this area, there may be a future role for the state in this area. Empowering a group to use money from an assessment system such as New Hampshire’s would be a tentative step in that direction. Such a group could research a possible future role, and, if needed, plan the beginnings of an infrastructure.

Option 10: Create a "buy back" program for flu vaccine

- ***We do not recommend the creation of a "buy back" program at this time.***

Flu vaccine Buy-Back systems are one option that has been suggested to improve the incentives of providers to purchase enough vaccine and to re-distribute vaccine in times of need.⁶⁷ The interaction between two problems lead us to this conclusion, 1) the rapidly changing environment for flu production and distribution and 2) the need for research into specific levels of compensation for unused flu vaccine and distribution methods. If the compensation rates for unused vaccine in a buy back program are set too high, incentives are created for providers to overbuy and to hoard stocks of vaccine. This could lead to worse shortages and high costs to the state. If compensation rates are set too low they are unlikely to affect the market, but will cost the state money nonetheless.

Finding the right rate is critical to the success of such a program. But in the changing environment that appears to be likely with the increase in supply and in the number of providers finding the right rate will be difficult. It is recommended that, if inequities in distribution persist over the next few years, a pilot program be instituted that tests various rates and evaluates the effects of the rates before such a program is implemented.

Stakeholder interviews revealed serious problems with the buy-back idea, especially with respect to ensuring the cold-chain for the vaccine (Sanofi-Pasteur and Wyeth). The phrase "cold-chain" refers to the problem that flu vaccine must be kept at a certain temperature in order to remain effective. So to be confident that the flu vaccine is effective, there must be some way of assuring that the flu vaccine has been kept at correct temperature. The more people who handle the vaccine, the less likely you can assume it has been stored properly.

If the intention is to create a buy-back program that is used to re-distribute vaccine, there is the potential to redistribute vaccine that has been rendered ineffective if the vaccine had not been consistently kept at correct temperatures. Since there is no way to monitor the care of the vaccine once it has been placed in the provider's offices, there would be no easy way to ensure that the vaccine remained efficacious, unless each container of vaccine came equipped with an individual temperature monitoring device.

Another variation on the buy-back option is for the state to purchase unused vaccine at the end of the flu season. This plan would encourage manufacturers to produce more vaccine than they believed they could sell, to provide a cushion for the annual supply in case of any manufacturing problems. If there were no problems in a given year, the extra vaccine expenditure would be a public rather than a private expense and would not discourage production in subsequent years.⁶⁸

Option 11: Create a public financing system for providers' purchase of vaccines

- ***We do not recommend creating a new financing system.***

This policy could address some of the needs of the providers. Manufacturers tell us that they already provide windows of time before providers must pay them back, though some appear to be inadequate to the needs of the provider. Establishing a state system would likely “crowd out” these private systems in Maryland, raising overall costs. A costly bureaucracy would have to be built to administer such a program. It is believed that the benefits of such a program can be better achieved with other policies.

Option 12: Mandate that flu vaccine distribution favor the “medical home.”

- ***We do not recommend a legislative mandate that flu vaccine distribution favor the “medical home.”***

In some states bills have been introduced to try to mandate such a system. We have found that increasing flu vaccine supply and increasing demand will mean that many venues should be used to distribute flu vaccine. Although the past distribution may have been inequitable, it is not clear what a future equitable system will look like. Medical homes will not suffice and legislation that tried to right past inequities is likely to cause unforeseeable consequences and more and perhaps greater distribution problems.

Manufacturers indicated during the stakeholder interviews that they would be opposed to legislation which mandated favoring the medical home for flu vaccination. It was their contention that high risk individuals seek access to flu vaccinations through multiple channels, including the retail providers. If flu vaccines were distributed to medical homes primarily, it is the manufacturers’ belief that there would be missed opportunities to vaccinate in the high risk population. Given the small proportion of vaccine delivered to the retail provider and the expected large increase in the future production vaccine, it would seem that this type of mandate would be too restrictive. We believe a broad-based policy recommendation to encourage flu vaccination wherever convenient for the consumer, especially in combination with a mandatory vaccine registry, would be more effective in preventing flu in the long run.

Option 13: Create a public reporting system that requires flu vaccine manufacturers and distributors to periodically inform the state of shipments into the state or orders from the state.

- ***We do not recommend this option.***

Because of the complex network of flu distribution that now exists, it is likely that this would be a costly option. Reports from all distributors about vaccine shipped would be required and then aggregating and accounting for doses that were sent through multiple distributors would create additional costs. It is not clear that the resulting reports would be accurate or timely enough to be worth the cost. A representative for Sanofi Pasteur indicated that they could provide information about shipments by zip code but that, while they ship most of their flu vaccine product directly to providers, other manufacturers make use of many distributors. The representative also indicated that Sanofi-Pasteur considered information about orders to be proprietary information.⁶⁹

Our survey showed that providers receive vaccines from dozens of sources. Trying to account for supply in the current conditions would be costly and the findings would likely not be timely enough to be used in effective policy making.

These difficulties and costs seem formidable, but we are still investigating whether there may be benefits that outweigh these problems.

Option 14: Provide flu vaccine at no cost to health care workers.

- **We do not recommend this option.**

Evidence from our stakeholder interviews leads us to believe that many health care workers are already offered flu vaccine at little or no cost and that cost is not a significant factor in workers choice. The state would only be subsidizing the workers' employers if it chose this option.

Option 15: Mandate all insurance companies and Medicaid to use one billing form (paper and electronic) for well-child and vaccines and create a way that this form could transmit data to the registry, so that vaccine information needs only to be entered once.

- **We do not recommend this option.**

Although there could be benefit in such a system, our study of the issue finds that it is so complex that any mandate is likely to have unintended consequences. It is possible that through strengthening the registry, creating incentives for registering immunizations, and other means, the state could slowly lead practices and health plans to more rational practices without a mandate.

Option 16: Insurance mandates eliminating co-payments and deductibles for adult flu vaccines.

- **We do not recommend this option at this time, though the situation should be monitored.**

There is much to recommend in this option. Our logic is similar to the reasoning we used for requiring Health Plans to cover children's immunizations with "first dollar" coverage, but in this case we reach a different conclusion. Flu immunizations benefit not only those who get them but also many of those who will be in contact with them. Unlike other medical procedures, most immunizations have such a large benefit to others that their use should be encouraged and not discouraged by the society. The reasons for co-payments and deductibles are to shift costs to the insured and to discourage over use of a product or service. That is not a concern with child immunization. It may still be a concern with flu vaccine until a more steady supply can be assured.

There are those who are not in a recommended group for flu vaccine. Overuse in this group should not be encouraged and such mandates may create such encouragement.

Option 17: Require all manufacturers to disclose their pricing arrangements

- ***We do not recommend this option.***

Vaccine manufacturers not only offer bulk pricing deals to governmental entities but to others who buy in bulk. This practice does discriminate against the small practices that are not part of a buying cooperative.

Vaccine manufacturers that we interviewed indicated that they believed that contractual information about such buying arrangements was “confidential information and may not be disclosed.” The small benefit of such information would likely not be worth the legal fight it might engender.

Appendix A: Stakeholders and Experts Interviewed

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Sarah Landry
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Harvard Medical School, Harvard Pilgrim Health Care, and Children's Hospital Boston

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President
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Elizabeth Liebow, MPH
Guest MedChi, Public Health/ Maternal and Child Health Joint Committee Meeting

Dean Mason
Asst Vice President
Wyeth Vaccine Global Policy

Charles Medani, M.D.
Pediatric Medical Director
CareFirst BlueCross. BlueShield

Jay Middleton
Director
Wyeth Government Affairs

Bob Morrison, Vaccine Manager
Massachusetts Department of Public Health

Cheryl Naylor, VFC coordinator
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Rhode Island Dept of Health

Dr. Harry Oken
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Appendix B: Results of the Survey of Vaccine Providers

Medical practices that might provide immunizations were identified in three ways. First, a list of all VFC providers was obtained. Most of the respondents (353 of 422) were identified through that list. Second, the public, internet-based list of MedChi members was used to identify telephone numbers of additional practices listed as pediatric specialists. Twenty-two additional practices were contacted through that the MedChi list (though 12 of those were also VFC participants). Thirdly, the list of MedChi members was used to generate an additional 47 practices that were identified as family practice specialists.

Respondents were asked a variety of questions about the medical practices in which they worked. The substantive questions are presented below, along with a summary of the responses given to those questions and the frequency with which those responses were given.

Question 1

I understand that you have been working with the Vaccines for Children (VFC) program and that through that program you have received some publicly purchased vaccines. Do you still participate in the VFC program?

(Asked of 353 practices that were contacted through the VFC participation list)

Response	Frequency of Response	Percent
1. Yes	351	99.4
2. No	2	0.6

Question 2

Do you participate in the state's VFC -- Vaccines for Children program?

(Asked of the 22 practices that were on the pediatric specialty list but had different phone numbers than the VFC participation list)

Response	Frequency of Response	Percent
1. Yes	12	54.5
2. No	9	40.9
3. Don't know	1	4.5

Question 3

How difficult is it to manage both private and public vaccine supplies? Would you say it is?

(Asked of the 365 practices that indicated they had participated in the VFC program)

Response	Frequency of Response	Percent
1. Not difficult at all	276	75.6
2. Somewhat difficult	68	18.6
3. Quite difficult	20	5.5
4. Don't know	1	0.3

Question 4

Are your publicly provided vaccines delivered in a timely manner?

(Asked of the 365 practices that indicated they had participated in the VFC program)

Response	Frequency of Response	Percent
1. Yes	308	84.4
2. No	52	14.2
3. Don't know	5	1.4

Question 5

From what suppliers does your office buy its privately purchased vaccines?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Names of 46 different supply channels (including manufacturers) could be categorized from the verbatim responses to this question.

Question 6

About how often do you get deliveries of privately purchased vaccines? Would you say...

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Daily	5	1.3
2. A few times a week	14	3.6
3. Weekly	45	11.4
4. A few times a month	94	23.9
5. Monthly	112	28.4
6. Every few months	86	21.8
7. Less often than every few months	19	4.8
8. Don't know	19	4.8

Question 7

Do you ever have problems getting these deliveries in a timely manner?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	75	19.0
2. No	308	78.2
3. Don't know	11	2.8

Question 8

In the past two years, have ever had to discard vaccines because of refrigeration failure?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	51	12.9
2. No	341	86.5
3. Don't know	2	0.5

Question 9

Has the high cost of some vaccines caused your office to not offer certain kinds of vaccinations to patients?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	148	37.6
2. No	238	60.4
3. Don't know	8	2.0

Question 10

How much of a financial burden has it been for your office to stock and maintain adequate supplies of vaccine?

On a scale of 1 to 10, with one being no financial burden at all and ten being a very large financial burden, how big a burden would you say this is?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Not a burden	119	30.2
2.	10	2.5
3.	22	5.6
4.	16	4.1
5.	42	10.7
6.	40	10.2
7.	22	5.6
8.	30	7.6
9.	9	2.3
10. Very large burden	59	15.0
11. Don't know, can't say	25	6.3

Question 11

How concerned are you about the risk of financial loss, which could be caused by a problem with the storage of these expensive vaccines.

On a scale of 1 to 10, with one being not at all concerned and ten being very concerned, how concerned would you be about the risk of financial loss?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Not at all concerned	128	32.5
2.	22	5.6
3.	16	4.1
4.	14	3.6
5.	30	7.6
6.	30	7.6
7.	13	3.3
8	18	4.6
9.	8	2.0
10. Very concerned	95	24.1
11. Don't know, can't say	20	5.1

Question 12

In the last 12 months, has your office had to postpone a child's scheduled vaccination because vaccines you would normally supply were not available from distributors?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	233	59.1
2. No	158	40.1
3. Don't know	3	0.8

Question 13

In the last 12 months, about how often have you had to postpone a vaccination because of unavailable vaccines? Would you say...

(Asked of the 233 practices that responded "yes" to the question above)

Response	Frequency of Response	Percent
1. A few times	147	63.1
2. More than a few times	66	28.3
3. About half the time	9	3.9
4. Even more than half the time	11	4.7

Question 14

On average, how long would you say these episodes of lack of supply last? Would you say...

(Asked of the 233 practices that responded "yes" to the question)

Response	Frequency of Response	Percent
1. A day or two	14	6.0
2. More than a few days	9	3.9
3. About a week	49	21.0
4. More than a week	34	14.6
5. A few weeks	65	27.9
6. More than a few weeks	57	24.5
7. Don't know	5	2.1

Question 15

This question is about all vaccines other than yearly flu vaccines.

In the last 12 months, about what percentage of vaccines that you store were discarded because they were not used before their expiration dates?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. NONE	211	53.6
2. 1-5 percent	146	37.1
3. 6-10 percent	0	0.0
3. 11-20 percent	31	7.9
4. 21-30 percent	3	0.8
5. 31 to 40 percent	0	0.0
6. 41 to 50 percent	2	0.5
7. Over 50 percent	1	0.3

Question 16

With the exception of the annual flu vaccine, in the past 12 months have you experienced any problems obtaining vaccines from vendors when you needed them?

(Asked of all 394 practices that indicated they administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	143	36.3
2. No	245	62.2
3. Don't know	6	1.5

Question 17

For each of the vaccines or diseases I mention, please tell me if you have experienced supply problems.

(Asked of the 143 practices that answered "yes" to the question above. Respondents could choose any or all responses, so the number indicated is the number of practices who indicated supply problems with that vaccine).

Response	Frequency of Response	Percent
1. DTP (or DTaP)	9	4.2
2. DT (or Td)	8	4.2
3. Polio	2	0.7
4. Hib	4	2.1
5. Hep B	6	1.4
6. Hep A	79	43.4
7. PCV 7 (pneumococcal)	24	4.9
8. M M R	25	4.9
9. Varicella (Chicken Pox)	114	26.6
10. MCV (Meningococcal)	40	2.1
11. Gardasil (HPV)	22	2.8
12. Tetanus	7	0.7
13. Other	3	2.1

Question 18

How often is your practice faced with an underinsured patient who declines an immunization because it is too expensive?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Not often at all	330	83.8
2. More than a few times	43	10.9
3. Often	16	4.1
4. Don't know	5	1.3

Question 19

On average, how many patients do you immunize per month?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. NONE	5	1.3
2. 1-10	29	7.4
3. 11-20	29	7.4
4. 21-30	29	7.4
5. 31-40	23	5.8
6. 41-50	17	4.3
7. 51-60	24	6.1
8. More than 60	230	58.4
9. Don't know	8	2.0

Question 20

There is a proposal that the state of Maryland buy and distribute all the required children's vaccines - not just the vaccine for VFC children.

On a scale of 1 to 10, with one being not at all supportive and ten being very supportive, how supportive would you be of the state of Maryland establishing such a program?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Not at all supportive	23	5.8
2.	2	0.5
3.	4	1.0
4.	4	1.0
5.	17	4.3
6.	16	4.1
7.	10	2.5
8	13	3.3
9.	6	1.5
10. Very supportive	281	71.3
11. Don't know, can't say	18	4.6

Question 21

Do you think that such a program would help increase the number of children in your practice who are immunized in a timely manner?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	248	62.9
2. No	120	30.5
3. Don't know	26	6.6

Question 22

If your compensation for administering immunizations in such a program were the same as the fees you now get for immunizing VFC children would that cause a financial problem for your practice?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	100	26.7
2. No	213	56.8
3. Don't know	62	16.5

Question 23

How big a problem do you think that would be? Would you say it would be a . . .

(Asked of all the 100 practices that responded "yes" to the question above)

Response	Frequency of Response	Percent
1. Minor problem	63	63.0
2. Major problem, but one you would overcome	28	28.0
3. Major problem that you might not be able to overcome	8	8.0
4. Don't know	1	1.0

Question 24

Other proposals under consideration would implement a stronger immunization registry system in Maryland.

*Do you routinely enter immunization records into the state computer registry (ImmuNet)?
Would you say that you do it . . .*

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Always	68	17.3
2. Sometimes	34	8.6
3. Rarely	14	3.6
4. Never	268	68.0
5. Don't know	10	2.5

Question 25

If a child transfers to your practice from another practice, do you routinely use the immunization registry (ImmuNet) to find past immunization records? Would you say you do it . . .

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Always	80	20.3
2. Sometimes	28	7.1
3. Rarely	13	3.3
4. Never	265	67.3
5. Don't know	8	2.0

Question 26

Do you ever have problems using the Maryland immunization registry?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	26	6.6
2. No	348	88.3
3. Don't know	20	5.1

Question 27

Would a registry that was integrated with your vaccine ordering system make such a system more useful to you?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	259	65.7
2. No	90	22.8
3. Don't know	45	11.4

Question 28

Would the extra staff costs related to a mandatory electronic immunization registry system be a problem for your practice?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	138	35.0
2. No	217	55.1
3. Don't know	39	9.9

Question 29

How big a problem would you say it would be? Would you say it would be a ...

(Asked of the 138 practices that responded "yes" to the question above)

Response	Frequency of Response	Percent
1. Minor problem	44	31.9
2. Major problem, but one you would overcome	46	33.3
3. Major problem that you might not be able to overcome	40	29.0
4. Don't know	8	5.8

Question 30

On a scale of 1 to 10, with one being not at all supportive and ten being very supportive, how supportive would you be of Maryland establishing a mandatory electronic immunization registry?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Not at all supportive	86	21.8
2.	11	2.8
3.	6	1.5
4.	4	1.0
5.	62	15.7
6.	24	6.1
7.	12	3.0
8.	12	3.0
9.	2	0.5
10. Very supportive	162	41.1
11. Don't know, can't say	13	3.3

Question 31

I have a couple of questions about administrative fees that your office receives for immunizing children.

Are the administrative fees your office receives for administering these vaccines adequate to cover the actual costs of administration?

(Asked of all 394 practices that indicated they have administered pediatric vaccines)

Response	Frequency of Response	Percent
1. Yes	217	55.1
2. No	105	26.6
3. Don't know	72	18.3

Question 32

About what percentage of the actual cost of administration do you think your fees cover?

(Asked of the 105 practices that responded "no" to the question above)

Response	Frequency of Response	Percent
00 percent	6	5.7
01 percent	1	1.0
02 percent	1	1.0
03 percent	1	1.0
05 percent	15	14.3
06 percent	1	1.0
10 percent	9	8.6
20 percent	10	9.5
25 percent	3	2.9
30 percent	3	2.9
39 percent	1	1.0
40 percent	6	5.7
50 percent	24	22.9
60 percent	5	4.8
70 percent	2	1.9
75 percent	9	8.6
80 percent	4	3.8
85 percent	1	1.0
90 percent	3	2.9

The mean response was 36.3 percent. The median of the responses was 40 percent.

Question 33

Have the inadequacies of the fees caused your office to rethink its vaccination procedures and/or policies?

(Asked of the 105 practices that responded "no" to the question before last)

Response	Frequency of Response	Percent
1. Yes	40	38.1
2. No	61	58.1
3. Don't know	4	3.8

Question 34

I would like to ask a few questions about two particular kinds of vaccines - flu vaccine and HPV vaccine, also known as Gardasil.

Do you routinely store Gardasil at your office?

(Asked of all 422 respondents)

Response	Frequency of Response	Percent
1. Yes	332	78.7
2. No	87	20.6
3. Don't know	3	0.7

Question 35

Do you think your office's choice not to store Gardasil is related primarily to the cost of the vaccine, or are there other considerations in the decision?

(Asked of the 87 practices that answered "no" to the question above)

Response	Frequency of Response	Percent
1. Cost	49	56.3
2. Other Considerations	36	41.4
3. Don't know	2	2.3

Question 36

In the last few years, have you experienced difficulties in obtaining annual flu vaccine for your practice?

(Asked of all 422 respondents)

Response	Frequency of Response	Percent
1. Yes	208	49.3
2. No	210	49.8
3. Don't know	4	0.9

Question 37

Have you ever had to refer patients to other providers to get flu shots?

(Asked of all 422 respondents)

Response	Frequency of Response	Percent
1. Yes	172	40.8
2. No	249	59.0
3. Don't know	1	0.2

Question 38

Why did you have to refer patients to other places to get flu shots? Would you say...

(Asked of the 172 respondents who answered "yes" to the question above. Respondents could choose any or all responses, so the number indicated is the number of practices who chose that response).

Response	Frequency of Response	Percent
1. You were not able to get enough vaccine from suppliers in a timely manner	152	88.4
2. You did not order enough vaccine because we underestimated the demand for it.	18	10.5
3. You do not ordinarily administer flu shots.	5	2.9
4. The patient's insurance did not pay for the shot and they could get it cheaper somewhere else.	11	6.4
5. Don't know, can't say	2	1.2

Question 39

If the state of Maryland guaranteed that it would buy back unused flu vaccine at 75 percent of what you paid for it, would you likely increase the amount of flu vaccine that you typically order?

(Asked of all 422 respondents)

Response	Frequency of Response	Percent
1. Yes	248	58.8
2. No	142	33.6
3. Don't know	32	7.6

Question 40

Do you think such a buy-back program would help you manage your flu vaccine inventory more effectively?

(Asked of all 422 respondents)

Response	Frequency of Response	Percent
1. Yes	266	63.0
2. No	125	29.6
3. Don't know	31	7.4

Appendix C: New Hampshire Vaccine Financing Law

CHAPTER 126-Q

NEW HAMPSHIRE VACCINE ASSOCIATION

126-Q:1 Definitions. In this chapter:

- I. "Association" means the New Hampshire vaccine association.
- II. "Commissioner" means the commissioner of the department of health and human services.
- III. "Covered lives" shall have the same meaning as defined in RSA 404-G:2, V.
- IV. "Estimated vaccine cost" means the estimated cost to the state over the course of a state fiscal year of the purchase, distribution, and administration of vaccines purchased at the federal discount rate by the department of health and human services.
- V. "Health insurance" shall have the same meaning as defined in RSA 404-G:2, VII.
- VI. "Licensed insurer" means any entity licensed pursuant to RSA 402, RSA 420-A, or RSA 420-B. "Licensed insurer" shall not include the New Hampshire Individual Health Plan Benefit Association.
- VII. "Total non-federal program cost" means the estimated vaccine cost less the amount of federal revenue available to the state for the purchase, distribution, and administration of vaccines.
- VIII. "Vaccine" means any preparations of killed microorganisms, living attenuated organisms, or living fully virulent organisms that are approved by the federal Food and Drug Administration and recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and have been authorized by the commissioner of the department of health and human services for administration to children of the state of New Hampshire under the age of 19 years for the purposes of producing or artificially increasing immunity to particular life-threatening and disabling diseases.

126-Q:2 Creation of Association. There is hereby created a nonprofit corporation to be known as the New Hampshire vaccine association. The association is formed to assess insurers for the cost of vaccines provided to certain children in New Hampshire.

126-Q:3 Membership, Powers, and Duties of the New Hampshire Vaccine Association.

I. The New Hampshire vaccine association shall be comprised of all licensed insurers currently writing or maintaining health insurance in New Hampshire.

II. The New Hampshire vaccine association shall be a not-for-profit, voluntary corporation under RSA 292 and shall possess all general powers of a not-for-profit corporation.

III. The board of directors shall include:

(a) Three representatives selected from the licensed insurers having the most covered lives in New Hampshire.

(b) Two health care provider representatives appointed by the commissioner.

(c) The commissioner of the department of health and human services, who shall serve as an ex-officio member.

(d) The commissioner of the department of insurance who shall serve as an ex-officio member.

IV. The directors' terms and appointments shall be specified in the plan of operation adopted by the New Hampshire vaccine association.

V. The board of directors of the association shall:

(a) Prepare and adopt articles of association and bylaws.

(b) Prepare and adopt a plan of operation.

(c) Submit the plan of operation to the commissioner of insurance for approval after the consultation with the commissioner.

(d) Conduct all activities in accordance with the approved plan of operation.

(e) On an annual basis, no later than November 1 of each year, establish the amount of the assessment.

(f) Enter into contracts as necessary or proper to collect and disburse the assessment.

(g) Enter into contracts as necessary or proper to administer the plan of operation.

(h) Sue or be sued, including taking any legal action necessary or proper for the recovery of any assessment for, on behalf of, or against members of the association or other participating person.

(i) Appoint from among its directors, committees as necessary to provide technical assistance in the operation of the association, including the hiring of independent consultants as necessary.

(j) Notify, in writing, each licensed insurer of the insurer's assessment by November 15 of each year.

(k) Submit an annual report to the commissioner of insurance listing those licensed insurers that failed to remit their assessments.

(l) Allow each insurer up to 90 days after the notification required by subparagraph (j) to remit its assessment or submit an assessment payment plan, subject to approval by the association and initial payment under an approved assessment payment plan.

(m) Deposit annual assessments collected by the association less the association's administrative costs with the state treasurer to the credit of the vaccine purchase fund established pursuant to RSA 141-C:17-a.

(n) Perform any other functions as may be necessary or proper to carry out the plan of operation.

126-Q:4 Assessment Determination.

I. The commissioner shall calculate the total non-federal program cost no later than October 1 of each year.

II. The board shall determine the amount to be raised by the association by multiplying the ratio of the number of covered lives to the total number of non-elderly New Hampshire residents by the total non-federal program cost.

III. For any year in which the total non-federal program cost exceeds 50 percent of the estimated vaccine cost, then the amount to be raised by the association shall be determined by multiplying the ratio of the number of covered lives to the total number of non-elderly New Hampshire residents by 50 percent of the estimated vaccine cost.

IV. Each licensed insurer shall be assessed in proportion to the number of its covered lives.

V. The aggregate amount to be raised by the association shall include credit for any surpluses remaining from prior years, as well as reasonable costs for the association's administration.

126-Q:5 Powers and Duties. In addition to the duties and powers enumerated elsewhere in this chapter:

I. The commissioner of insurance shall fine any licensed insurer that fails to pay an assessment within 6 months of notification under RSA 126-Q:3, V(j). The fine shall be at least \$5,000 and no more than 125 percent of the amount of the delinquent assessment. Fines so levied shall be deposited with the state treasurer to the credit of the vaccine purchase fund established pursuant to RSA 141-C:17-a.

II. The commissioner and the commissioner of insurance may adopt rules, pursuant to RSA 541-A, as necessary to carry out the purposes of this chapter.

126-Q:6 Examinations and Annual Reports. The board of directors shall submit to the commissioner, no later than 120 days after the close of the association's fiscal year, a financial report in a form approved by the commissioner.

126-Q:7 Exemption from Taxes. The association shall be exempt from payment of all fees and all taxes levied by this state or any of its subdivisions, except taxes levied on real property.

126-Q:8 Immunity from Liability. There shall be no liability on the part of and no cause of action of any nature shall arise against any association member or its agents or employees, the association or its agents or employees, members of the board of directors, or the commissioner or the commissioner's representatives, for any action or omission by them in the performance of their powers and duties under this chapter.

126-Q:9 Severability of Chapter. If any provisions of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the chapter which can be given effect without the invalid provisions or applications, and to this end the provisions of this chapter are severable.

279:3 Effective Date. This act shall take effect 30 days after its passage.

(Approved: May 18, 2002)

(Effective Date: June 17, 2002)

Appendix D: Proposed Bill in the General Assembly of North Carolina on Financing Universal Purchase

GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2007

Sponsors: Representative England.

Referred to:

HOUSE DRH60135-LNf-172B* (3/6)

Short Title: Immunization Changes.-AB (Public)

1 A BILL TO BE ENTITLED 2 AN ACT PERTAINING TO THE UNIVERSAL CHILDHOOD
IMMUNIZATION 3 PROGRAM IN THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES; 4 PROVIDING FOR ASSESSMENT OF HEALTH INSURERS FOR THE 5
PURCHASE, STORAGE, DISTRIBUTION, AND QUALITY ASSURANCE OF 6 CERTAIN
VACCINES; AND AUTHORIZING AN ADMINISTRATION FEE 7 FOR PROVIDERS
THAT ADMINISTER VACCINES. 8 The General Assembly of North Carolina enacts: 9

SECTION 1. Part 2 of Article 6 of Chapter 130A of the General Statutes is 10 amended by
adding the following new sections to read: 11 **"§ 130A-159. Universal Childhood**

Immunization Program; participation. 12 The Department shall include in the Universal
Childhood Immunization Program 13 those vaccines for childhood immunizations recommended
by the Advisory Committee 14 for Immunization Practices of the Centers for Disease Control
and Prevention (CDC) 15 and designated for coverage by the federal Vaccine for Children
Program. Physicians 16 providing these childhood vaccines shall participate in the North
Carolina Universal 17 Childhood Immunization Program administered by the Department. The
Department 18 shall allow each health care provider participating in the Program to select
vaccines 19 from a list of all vaccines that are (i) approved by the United States Food and Drug
20 Administration, (ii) recommended by the Advisory Committee on Immunization 21 Practices,
and (iii) made available under contract with the Centers for Disease Control 22 and Prevention.
23 **"§ 130A-159.1. Childhood Immunization Account established.** 24 There is created within
the General Fund a nonreverting restricted receipts account 25 to be known as the 'Childhood
Immunization Account.' All funds in the account shall 26 be used by the Department to
effectuate the provisions of G.S. 130A-159. All funds

General Assembly of North Carolina Session 2007

received pursuant to G.S. 130A-159.3 shall be deposited in the Childhood Immunization
Account. "§ 130A-159.2. Definitions.

As used in this Part, unless the context clearly requires otherwise:

(1) 'Covered life'. – Any person who is covered under a medical benefits plan that is insured
or administered by a health insurer.

(2) 'Covered life months.' – The number of months a covered life has coverage as a covered
life during a calendar year.

(3) 'Health insurer.' – Any entity that provides medical care benefits including, but not
limited to, excess or stop-loss insurance that covers medical care or administers medical care on

any individual in this State and operating under the authority of Chapter 58 of the General Statutes, for the benefits prescribed in G.S. 58-68-25(a)(5) and excluding the benefits excepted in G.S. 58-68-25(b).

(4) 'Insurer'. – Includes the following:

An insurance company;

A hospital or medical service corporation;

A health maintenance organization;

A multiple employer welfare arrangement;

A third-party administrator or claims processor;

The Teachers' and State Employees' Comprehensive Major Medical Plan; and

Any other nongovernmental entity providing a health benefit plan subject to State insurance regulation.

(5) 'Medical care.' – All of the following:

The diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the human body;

Transportation primarily for and essential to medical care as referred to in sub-subdivision a. of this subdivision.

Insurance covering medical care as referred to in sub-subdivision a. of this subdivision.

(6) 'Program'. – The Childhood Immunization Program administered by

the Department. "§ 130A-159.3. Assessment.

(a) Not later than June 1, 2007, and annually thereafter, the Department shall determine the dollar amount appropriate to purchase, store, distribute, and provide quality assurance for the following vaccines for routine immunizations, in accordance with the recommended application of the Advisory Committee for Immunization Practices of the CDC after June 1, 2007, for which a federal contract price has been established.

The Department shall make available to each health insurer, upon its request, information about the Department's Universal Childhood Immunization Program and the costs related to the Program. The Department shall submit to the General Assembly an annual report on March 1 on the Universal Childhood Immunization Program and costs related to the Program. The Department shall, by the same date, inform the Commissioner of Insurance of the dollar amount determined under this subsection.

(b) The Commissioner of Insurance shall, after notice and opportunity for hearing, determine the annual health insurer assessment for the purchase, storage, distribution, and quality assurance of vaccines listed in G.S. 130A-159.3 and shall issue an order to that effect. The order shall be issued no later than September 1. The annual assessment shall be based on the number of covered life months in the year prior to the assessment.

(c) All health insurer assessments shall be submitted by the health insurer to the Department on or before March 31 of each year. A health insurer whose assessment is greater than one million dollars (\$1,000,000) for the year shall be assessed in four quarterly payments of twenty-five

percent (25 percent) of its total assessment. Quarterly assessments are due on the first business day of January, April, July, and October of each year. Any funds collected in excess of funds needed to purchase, store, distribute, and provide quality assurance for the vaccines shall be deducted from the subsequent year's assessment.

(d) For new vaccines recommended by the Advisory Committee for Immunization Practices of the CDC for which an initial federal contract price is established between June 1 and March 31 of subsequent fiscal years, an interim assessment will be made. The Department shall determine the dollar amount appropriate to purchase, store, and distribute the new vaccine and shall inform the Commissioner of Insurance of the dollar amount by the first day of the quarter of the year following the establishment of a federal contract price for the vaccine. The Commissioner of Insurance shall determine the appropriate health insurer assessment within 90 days of receiving notice of this amount from the Department. All health insurer assessments for the new vaccine shall be submitted to the Department within 90 days of receiving the assessment from the Commissioner of Insurance. An insurer whose assessment for the new vaccine is greater than one million dollars (\$1,000,000) shall be assessed prorated quarterly payments. "§ 130A-159.4. Administration fee.

The Commission shall establish by rule a reasonable administration fee to be reimbursed by health insurers to any provider, including a local health department, that administers a vaccine included in the Program."

SECTION 2. Article 3 of Chapter 58 of the General Statutes is amended by adding the following new section to read: "**§ 58-3-262. Universal Childhood Immunization Program requirements.**

(a) As used in this section:

(1) 'Covered life month.' – Same meaning as in G.S. 130A-159.2.

(2) 'Health insurer.' – Same meaning as in G.S. 130A-159.2.

(b) The purpose of this section is to provide the Commissioner with information necessary for the Commissioner to determine the assessment required by G.S. 130A-159.3.

(c) Every health insurer that is subject to the Universal Childhood Immunization Program shall annually report to the Commissioner the number of covered life months insured or administered by the health insurer during a period and on a form prescribed by the Commissioner. The Commissioner shall determine the date on which the annual report is due.

(d) The Commissioner may adopt rules to carry out the purposes of this section." SECTION 3. This act is effective when it becomes law.

**Appendix E: Genesis HealthCare Employee Voluntary
Consent/Declination for Influenza Vaccine**

Genesis HealthCaresm

**EMPLOYEE VOLUNTARY CONSENT/DECLINATION
FOR INFLUENZA VACCINE**

(State of Maryland Only)

Center Name: _____

Employee Name: _____ Employee ID#: _____

Please check the appropriate box:

☐ I have been instructed regarding the benefits and risks of receiving the influenza vaccination. I know that I **may** experience some side effects, such as:

- ◆ Slight generalized discomfort
- ◆ Soreness or redness of the arm
- ◆ Slight fever and/or muscle aches

☐ **I hereby request an injection of influenza virus vaccine.**

☐ To the best of my knowledge, I have had an allergic reaction or anaphylactic reaction from the influenza vaccination in the past and therefore

☐ I **decline** to have it.

☐ For religious reasons,

☐ I **decline** to have the influenza vaccination. _____

☐ I **decline** to have the vaccination due to _____

Signature of Employee

Date

Signature of Vaccinator/Nurse

Date

Appendix F: Further Explanation of Cost Estimation Methodology for the Implementing a Universal Vaccine Purchasing System in Maryland

There are various ways to estimate the cost of a Universal Vaccine Purchase program to the state of Maryland. The Schaefer Center research team based its estimate on three key pieces of information: 1) an estimate of which vaccines would need to be purchased, 2) three different estimates of the price of these vaccines and 3) an estimate of the number of doses that would need to be purchased for each vaccine. This appendix lays out the various assumptions we used, as well as our basis for each assumption.

As part of the ongoing accumulation and assessment of information about the vaccine distribution in Maryland, it was determined from Mr. Edward Hirshorn (Chief of the Vaccines for Children Program in Maryland) that there were differences in the Vaccine For Children participation rates by age. We originally tried to develop cost estimates of universal purchase systems by using a single estimate of the percent of children covered by private health insurance. The number of children whose vaccines are not now provided by public sources was critical to our estimates because those would be the children whose vaccine costs would be picked up by the state in a system of universal purchase. It was assumed that the other children now covered by federal programs would still be covered by federal programs.

Edward Hirshorn had been contacted because we were attempting to reconcile the Massachusetts Public Health Association's estimate of \$61.5 million for a Universal Purchase system that included HPV vaccine (see footnote 45 in the original report) with other estimates that we had seen and the estimates we had calculated. Since Massachusetts' population is about 10 percent greater than Maryland's, the Massachusetts estimate would approximately equate to a cost of \$55 million if the purchase were to be made through the CDC contract in Maryland. This news of an age differential in participating in VFC promised to solve the reconciliation problem between other states' estimates and our initial estimates.

Step one: We took the fax sent by Edward Hirshorn on October 30 (see reproduction below), of his report entitled "Twelve Month Vaccine Ordering Report for the Grantee Working Draft for Grant Year 2008 for Maryland with Wastage" and transcribed the following 6 columns into a spreadsheet: 1) Vaccine name, 2) Brand name of vaccine, 3) number of doses to be ordered by the state of Maryland for VFC children in 2008, 4) cost of doses ordered for VFC children in 2008, 5) number of doses ordered by state of Maryland under 317 section for children in 2008 and 6) cost of doses ordered under 317 in 2008.

Mr. Hirshorn's report contains data on all of the brand name vaccines that will be ordered by the Massachusetts state program through the CDC contract. His report forms the basis of Table 10 and Table 11 in the final report. The template is identical to the columns E, F, G and H in the spreadsheet named "Cost Estimates 10 30 07.xls."

Twelve Month Vaccine Ordering Report For The Grantee Working Draft For Grant Year 2008 For Maryland With Wastage

Vaccine		VFC		Dose	317	State/Local	
		Dose	Cost			Cost	Cost
DTaP	Infanrix®	42,50	\$563,127	222	\$12,799	0	\$0
DTaP-Hib	TriHibit®	21,24	\$550,542	743	\$19,252	0	\$0
DTaP	Tripedia®	6,238	\$78,911	334	\$4,230	0	\$0
DTaP - IPV- Hepatitis B	Pediatrx®	84,67	\$4,000,982	4,488	\$212,052	0	\$0
DTaP	DAPTACEL®	40,28	\$533,805	4,681	\$62,024	0	\$0
Influenza	Fluzone®	83,05	\$843,207	700	\$7,107	0	\$0
Influenza- Preservative Free Pediatric	Fluzone®	105,000	\$1,340,850	700	\$8,939	0	\$0
Influenza (Live, Intranasal)	FluMist®	44,250	\$781,013	736	\$12,986	0	\$0
Hepatitis A Pediatric	Havrix®	71,141	\$871,472	2,169	\$26,574	0	\$0
Hepatitis A Pediatric	VAQTA®	71,142	\$871,484	2,099	\$25,717	0	\$0
Hepatitis B - Hib	COMVAX®	3,855	\$106,975	850	\$23,580	0	\$0
Hep B Preservative Free Pediatric	ENGRIX-B®	29,990	\$272,913	2,069	\$18,831	0	\$0
Hep B Preservative Free Pediatric	RECOMBIVAX HB®	25,102	\$238,471	1,999	\$18,994	0	\$0
Hib	ActHib®	69,297	\$573,780	6,618	\$54,796	0	\$0
Hib	PedvaxHIB®	55,338	\$599,309	4,639	\$50,235	0	\$0
Human Papillomavirus	Gardasil®	106,596	\$10,313,175	6,582	\$636,80	0	\$0
Menococcal Conjugate	Menactra®	85,913	\$6,279,359	4,329	\$316,379	0	\$0
Measles, Mumps and Rubella	MMRII®	80,729	\$1,420,836	4,109	\$72,313	0	\$0
Pneumooccal conjugate	Prevnar®	173,146	\$10,759,274	6,224	\$386,761	0	\$0
Polio	IPOL®	71,200	\$787,476	5,348	\$59,152	0	\$0
Rotavirus, Live, Oral, Pertavalent	RotaTeq®	112,687	\$6,203,431	2,929	\$161,245	0	\$0
To Reduced Diphtheria Toxoid & Acellular Pertussis	ADACEL	38,757	\$1,230,528	1,806	\$57,337		\$0
To Reduced Diphtheria Toxoid & Acellular Pertussis	BOOSTRIX	28,065	\$862,998	1,209	\$37,182	0	\$0
Td	DECAVAC	3,182	\$55,303	274	\$4,761	0	\$0
Varcella	Varivax®	139,733	\$8,265,183	2,602	\$153,919		\$0
Grand Totals:		1,593,123	\$58,404,404	69,203	\$2,443,965	0	\$0
Percents:		95.83%		4.16%	0.00%		
		Doses:		1,662,326	Cost	\$60,848,369	

Step two: The data in the report provided by Mr. Hirshorn were checked to see if they were based on the latest available CDC price list. It was found to be so based. That price list was then used as the basis for the private cost estimates needed for our analysis. These prices are reported in Columns F and H of Tables 10 and 11. These prices are available at <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>).

Step three: The percent of children in the private sector who would be likely to use each vaccine in the next year was estimated.

- i. Estimates of the population for each of the different age ranges used by the VFC program were provided by Mr. Hirshorn in a phone call on Oct. 30, 2007; These were inserted in the "Population Estimate" sheet (rows 1 through 5 of the spreadsheet labeled "Table 10 background.xls").
- ii. The CDC recommended ages for each vaccine were referenced. (These are available at <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2007/child-schedule-color-print.pdf>).

iii The calculations in Sheet 1, column I were determined by using the recommended ages for doses of the vaccine and multiplying by the populations in the respective age ranges in Maryland's population.

For example, all Hepatitis B doses are recommended in the first year of life. The percent of the 'under one year of age' population that now receives this vaccination in the private sector is 37.12 percent ("Table 10 background.xls" Sheet "Population Estimate" Column F), that percent was then used in column I. Since the recommended ages for Flu and MMR spanned more than one of the age ranges, a weighted average was constructed for each of these. For MMR, for example, it was assumed that half would be in the 1 to 2 age range and half in the 3 to 6.

Step four: It was assumed that, if the state were to implement a Universal Vaccine Purchase System, the new use of all vaccines in the (now) private sector would be the same as the use in the existing public sector. This is the primary assumption that is different between Table 10 and Table 11. Table 10 assumes that the use rate in the private sector will match that in the public sector, while Table 11 assumes that the universal purchase program will increase demand in the private sector, leading to an increased utilization rate overall.

With these assumptions we estimated the required new doses by 1) adding the official estimate of the doses needed for VFC and the doses needed for 317 children (column E and Column G of "Table 10 background.xls") then 2) dividing the sum by the estimated percentage that those children represent in the overall demand for that vaccine (1- column I) (this resulted in an estimate of the number of doses needed in both the public and private sectors) and subsequently 3) multiplying the result by column I, which then gave an estimate of the doses required for the newly added who were formerly in the patients private sector. The result is column J.

Step five: Column J, the estimates of the new doses that would have to be supplied by the state under universal purchase, were multiplied by the CDC costs, which are reported on the CDC website referenced in Footnote 46 for vaccines purchased through the CDC (Column K multiplied by Column J, creating Column L) and for vaccines purchased at the price the CDC calls the "private sector cost/dose" (Column M multiplied by Column J, creating Column N).

Step six: The previous five steps produced an upper and lower bounds on the cost estimate. The lowest cost estimate was produced by multiplying the required number of doses by the CDC vaccine prices (resulting in Column L) and the highest cost estimate was produced by multiplying the private vaccine prices that are reported on the CDC website (resulting in Column N). To get a point estimate of the estimated cost that reflects the potential ability of the state to negotiate lower rates with the vaccine manufacturers than the private prices reported on the CDC website was still required. Using the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) statement that their participants save, in general, about 23 percent of the Average Wholesale Price (source: <http://www.cga.ct.gov/2005/rpt/2005-R-0724.htm>) but also understanding that vaccines do not usually get the highest discounts, it was assumed that the private price would be discounted by 23 percent to estimate the Purchase system price. However, where this assumption resulted in the projected price being below or very near the CDC price, it was assumed that negotiations would reach a price that was closer to the CDC price than to the private price. For those vaccines (the flu vaccines, Gardasil, Menactra, Prevnar, ADACEL, RotaTeq, BOOXTRIX, DECAVAC, and Varivax) the price was estimated to be the CDC price plus one-third of the difference between the CDC price and the private sector price.

Step seven: The final step in estimating a simulated a midpoint price (Column P) that could be obtained using a group discount such as the MMCAP was to multiply this new estimate of a discounted price [Step six] by the number of estimated new doses needed to supply the private sector (Column J multiplied by Column O) to create Column P.

The individual vaccine cost estimates from Column P were added together to produce a grand total cost estimate. This point estimate of the total vaccine costs represents what we believe to be the best estimate given the available information if Maryland were to adopt a universal purchase program where, (1) the state is not able or is not willing to use the CDC contract prices for the children who are not VFC or 317 eligible, but (2) is able to negotiate a discount from the manufacturers either through a purchasing alliance or directly.

These estimates appeared to be superior because the estimates produced in step six for the estimate of the cost when using the CDC contract almost exactly matched a population adjusted estimate of Maryland's cost based on Massachusetts' official estimate that had been made earlier in the year of what it would cost to fully implement a Universal purchase program in that state (and Massachusetts has long experience with universal purchase). This method of estimation also used more precise data on the rate of participation in VFC and 317 programs than had been used in our prior estimates or state reports done by others (such as the New Jersey report).

Following the submission of the preliminary final report, the Commission met on November 13, 2007 to discuss the report and to discuss which recommendations the Commission might make. Dr. McGrath of our research team attended and was available to answer questions. Two specific areas of concern with the recommendations made by the research team were communicated to him at that time. One involved the lack of specificity in the findings and the recommendations about policies related to provision of HPV vaccine. This was addressed in the revisions made to the report and submitted on November 30.

In addition to this concern, concern was expressed that an estimate of the likely cost had been submitted that assumed that demand for vaccine in the now-private sector would equal current demand in the publicly provided sector once universal purchase was implemented. Though no one disputed that this estimate was a valid one, there was a request that Dr. McGrath understood to be a request to use an assumption of the highest possible demand under universal purchase. It was argued that the state should be concerned not only about likely costs but about the highest potential costs of implementing such a program. Dr. McGrath agreed that the team would use the new assumption about demand and produce a companion analysis that was labeled "potential cost." The result was Table 11 in the final report.

Our understanding from this discussion was that the Commission wanted to see what the total cost to the state could be, given the assumption that **all** Maryland children would receive the complete series of vaccines that have been recommended by the CDC. Previously the models had assumed that private sector demand generated by a new Universal Purchase program would be equivalent to the current VFC estimates of utilization rates in the public sector. The team's understanding was that these newly requested estimates were not to be in place of the others in the preliminary final report, but as supplements to them. This was assumed because when Dr. McGrath asked the Commission if they agreed with his assumption that utilization rates in the private sector would be equivalent to the actual public sector rates and would produce a more accurate projection, there was one assent and no objection.

In response to the Commission's request that projected "potential costs" be calculated, Table 11 was added to the final report. The calculations upon which Table 11 is based are in the file "Table 11 Projections of Possible Costs.xls" (attached). The difference between Tables 10 and 11 are produced by the assumed different demand responses following implementation of the Universal Purchase Program.

The demand response used in Table 11 can be decomposed into two components: (1) demand changes specific to the relatively new Gardasil vaccine, and (2) demand changes for other vaccines. Gardasil demand is identified separately because compared to other recommended childhood vaccines it now has the lowest uptake rates and has the potential for a large increase in demand. Also, since it has been recently recommended and has not yet had uptake rates, many older children have not yet been vaccinated. Our estimates are annual projections for the next few years and are sensitive to this kind of "one-time" demand. These potential increases in demand would also create significant increases in the costs of the program because of the relatively high cost of Gardasil. This is shown by the fact that, once an assumption of the highest possible demand is made, this one vaccine accounts for 47 percent of the Table 11 potential total cost of the Universal Purchase Program.

Step one: The primary differences between Table 10 and Table 11 are generated by the difference in the column labeled "Estimated Number of doses distributed in the private sector" in Table 10 and the column labeled "Potential number of doses distributed in the public sector" in Table 11. For all vaccines except Gardasil, a 100 percent utilization general rate was assumed in Table 11. It was estimated that general uptake rates of vaccines other than Gardasil averages

about 95 percent. Thus all estimates of doses needed for the public sector in Table 10 were increased by 5 percent to get a "potential utilization rate."

Step two: Estimating Gardasil's potential utilization rate was a multi-step process. Mr. Hirshorn's data reported that there were 528,731 children estimated to be in the age range 7 to 18 in the private sector. It was estimated that half of these children were female. We estimated that half of this population was age ineligible or would have already have received the vaccine by the time the program was implemented. The remaining eligible population was 132,183.

The recommended number of doses per child is three. It is thus possible (though unlikely) that each of these girls could receive all three doses in a year. Thus the potential number of Gardasil doses needed was calculated to be 396,548. This upper bound of utilization resulted in a total "Potential Cost" due to Gardasil alone of \$41,505,413, which is 47 percent of the total "Potential Cost" of \$88,889,216 (Table 11).

The other calculations in Table 11 make the same assumptions and employ the same steps as in Table 10. As can be seen in the Summary Table below, the primary difference in the cost estimates between Tables 10 and 11 is determined by the dosing frequency and the very high cost of the Gardasil vaccine.

Summary Table Comparing the Contents of Tables 10 and 11

	Table 10 Cost Estimates: Assumes private sector demand will be equivalent to current public sector demand	Table 11 Cost Estimates: Assumes private sector demand will be 95% of eligible population
Estimated Total Costs using only Public Sector CDC Prices	\$55,397,404	\$78,875,063
Estimated Total Costs using only Private Sector Prices	\$74,398,967	\$103,829,328
Estimated Total Costs assuming State negotiates a discounted rate with a Purchasing Alliance WITH GARDASIL	\$63,376,219	\$88,889,216
Estimated Total Costs assuming State negotiates a discounted rate with a Purchasing Alliance WITHOUT GARDASIL	\$46,783,252	\$47,383,803

Appendix G: Twelve Month Estimate of the continuing cost of reimbursing providers for entering antigens into the Maryland Immunization Information System in 2008

The table below is once again derived from the Maryland VFC program's estimates used in the "Twelve Month Ordering Report for Grant Year 2008 for Maryland With Wastage." (See Appendix E).

The table takes the information from that source about the number of estimated doses that will be distributed to VFC eligible children in 2008 and the number of eligible doses that will be distributed through the 317 program for each vaccine supplied by the state. For the number of doses that will be distributed in the public sector, the same calculations described in Appendix E are made. The next step is to add these numbers up to estimate the total doses that will be administered in the state. The next step counts the number of antigens in each vaccine and then multiplies that number times the estimate of the number of doses of that vaccine that will be administered. This number is totaled for all vaccines and multiplied by the hypothesized reimbursement factor of \$0.50 to get the projected cost of registering new vaccines in 2008.

Vaccine	Brand Name	Estimated VFC Doses for 2008	Estimated 317 Doses for 2008	Estimated private sector doses for 2008	Estimated total doses that will be administered in 2008	Number of Antigens	Estimate of antigens administered in 2008 (Antigens times Doses)	Proposed reimbursement
DTaP	Infanrix	42,500	966	25,661	69,127	3	207,381	
DTaP-Hib	TriHIBit	21,248	743	12,983	34,974	4	139,896	
DTaP	Tripedia	6,238	334	3,880	10,452	3	31,356	
DTaP-IPV-Hepatitis B	Pediarix	84,677	4,488	52,641	141,806	5	709,028	
DTaP	DAPTACEL	40,287	4,681	26,548	71,516	3	214,548	
Influenza	Fluzone	83,050	700	64,258	148,008	1	148,008	
Influenza-Preservative Free	Fluzone							
Pediatric	pediatric	105,000	700	81,099	186,799	1	186,799	
Influenza (Live, Intranasal)	FluMist	44,250	736	39,606	84,592	1	84,592	
Hepatitis A Pediatric	Havrix	71,141	2,169	58,340	131,650	1	131,650	
Hepatitis A Pediatric	VAQTA	71,142	2,099	58,285	131,526	1	131,526	
Hepatitis B-Hib	COMVAX	3,855	850	2,778	7,483	1	7,483	
Hep B Preservative Free								
Pediatric	ENGRIX-B	29,990	2,069	18,927	50,986	1	50,986	
Hep B Preservative Free	RECOMBIVAX							
Pediatric	HB	25,102	1,999	16,000	43,101	1	43,101	
Hib	ActHIB	69,297	6,618	44,818	120,733	1	120,733	
Hib	PedvaxHIB	55,338	4,639	35,409	95,386	1	95,386	
Human Papillomavirus	Gardasil	106,596	6,582	158,531	271,709	1	271,709	
Meningococcal Conjugate	Menactra	85,913	4,329	126,404	216,646	1	216,646	
Measles, Mumps, and Rubella	MMRII	80,729	4,109	71,020	155,858	3	467,575	
Pneumococcal conjugate	Prevnar	173,146	6,224	105,895	285,265	1	285,265	
Polio	IPOL	71,200	5,348	45,192	121,740	1	121,740	
Rotavirus, Live, Oral, Pentavalent	RotaTeq	112,687	2,929	68,257	183,873	1	183,873	
Td Reduced Diphtheria Toxoid & Acellular Pertussis	ADACEL	38,757	1,806	56,818	97,381	3	292,142	
Td Reduced Diphtheria Toxoid & Acellular Pertussis	BOOXTRIX	28,065	1,209	41,005	70,279	3	210,837	
Td	DECAVAC	3,182	274	4,841	8,297	2	16,594	
Varicella	Varivax	139,733	2,602	119,153	261,488	1	261,488	
Grand Totals		1,593,123	69,203	1,338,347	3,000,673		4,630,342	\$0.50

Total Projected Cost
(Reimbursement per antigen
times estimate of antigens that
will be administered)

\$2,315,171.00

Appendix H: Some Details of the Regression Analyses Conducted for the Study

Many exploratory analyses were conducted to see if a statistically significant difference could be found between those states that have purchased vaccines for all the children of their state and those states that administer a program similar to the program run currently by the state of Maryland and labeled by the CDC as "VFC enhanced" program.

Many standards from the National Immunization Survey results were used as dependent variables in these analyses. In the list of dependent variables below the first number indicates the number of DTP (Diphtheria, Tetanus, Pertusis) shots required to be up-to-date for 19 to 35 month old children for the standard to be met, the second number indicates the doses of polio vaccine needed, the third number MMR (Measles, Mumps, Rubella), the fourth number *Haemophilus influenzae* type B, the fifth number, Hepatitis B, and the sixth number, varicella. The year after these numbers indicates the year of the NIS survey in which this standard was calculated.

Dependent variables included:

4:3:1:3:3:1

4:3:1:3:3

4:3:1:3

4:3:1

4 DTP alone

3 polio alone

1 MMR alone

3 *Haemophilus influenzae* type B alone

3 Hepatitis B alone

1 varicella alone

3 Pneumococcal Conjugate Vaccine alone

4 Pneumococcal Conjugate Vaccine alone

Each of these dependent variables was examined for each year of the data (5 years) making 60 dependent variables that were examined.

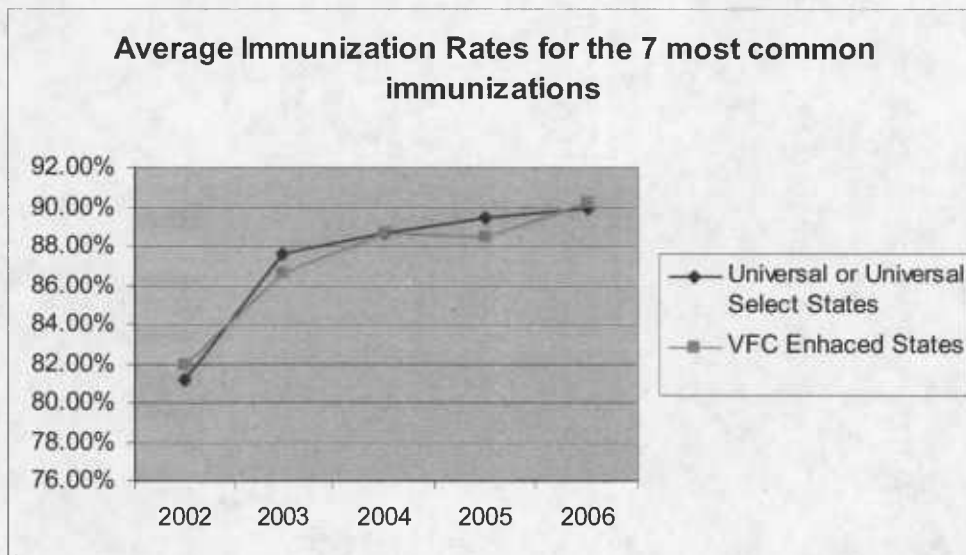
The "policy" variable was a dichotomous variable which was valued 1 if the state had been a universal vaccine purchasing state for these vaccines for the past 5 years and 0 if the state was a

VFC enhanced state. There were 15 states classified as universal purchase under this criterion and 10 states classified as VFC enhanced.

Other independent variables were population density as of the 2000 census, the percentage of children in the state living in poverty, the percentage of children in the state who are uninsured. These were used as control variables and were tested in a regression equation and partial correlation scores were examined.

As would be expected with so many dependent variables a few of the relationships were statistically significant at the .05 level. For example, being up to date with 4 DTP doses in 2006 was statistically significant and a positive relationship with being a universal purchase state. On the other hand, being up-to-date for 3 polio doses in 2006 was equally as statistically significant and was negatively related with being a universal purchase state. No patterns distinguishing the two types of states could be established, either alone or using the control variables.

To help best express these findings, a composite index of the average percentage of children 19 to 35 months up-to-date over these seven common childhood vaccines in a state was constructed for each year. That percentage shows the trend over the past 5 years toward higher immunization rates, but shows practically no difference between universal purchase states and VFC enhanced states on this composite measure over time. The results are presented in the graph below.



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